IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* ELLSWORTH ASSOCIATES, LLP, Plaintiff-Relator, v. CVS HEALTH CORPORATION, *et al.*, Defendants.	Case No.: 2:19-cv-02553-JMY

RELATOR'S BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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TABLE OF CONTENTS

INTRODUCTION 1

STATEMENT OF FACTS 3

A. The False Claims Act 4

B. Medicare Part D 5

1. Sponsors Must Certify the Accuracy, Completeness, and Truthfulness of Claims Data Submitted to CMS 7

2. Part D Sponsors Must Have a Robust Compliance Program. 8

3. Part D Plans Must Provide Beneficiaries the Right to Seek Coverage Determinations and File Grievances. 8

4. Sponsors Must Advise Beneficiaries of the Cost Differential for the Lowest-Price Generic Alternative. 9

5. Sponsors Must Submit Accurate DAW Coding as Part of Each Claim 10

6. Sponsors Must Comply with State Mandatory Generic Substitution Laws 12

C. Defendants' Fraudulent Scheme 13

LEGAL STANDARD 15

ARGUMENT 16

I. ELLSWORTH HAS ADEQUATELY ALLEGED VIOLATIONS OF THE FALSE CLAIMS ACT. 16

A. Defendants Engaged in Anticompetitive Conduct That Defrauded the Government. 16

B. Relator Has Adequately Alleged False Certification Claims. 21

1. The SAC Adequately Alleges That Defendants Falsely Certified Their Compliance with State Mandatory Generic-Substitution Laws 23

i. Defendants' Falsehoods Were Material 27

ii. Defendants Acted Knowingly 29

2. Defendants Submitted False Claims by Using False DAW Codes. 31

3. The SAC Plausibly Alleges that Denying Formulary Exceptions Caused False Claims to Be Submitted 35

4. The SAC Plausibly Alleges Defendants' Fraudulent Marketing Caused the Submission of False Claims. 41
5. The SAC Plausibly Alleges Defendants Falsely Certified Compliance with Federal Laws and Regulations 49
6. The SAC Plausibly Alleges False Claims for Violations of the Firewall and FTC Consent Order 51

C. The SAC Adequately Alleges Conspiracy Claims 54

D. The SAC Is Not Barred by Public Disclosure 57
1. Relator's Allegations of Fraud Against Defendant Were Not Publicly Disclosed Prior to Relator's Action. 57
2. In Any Event, Relator Is an Original Source, Precluding Application of the Public Disclosure Bar. 60

E. CVS Health and CVS Pharmacy Are Proper Defendants. 64
1. The SAC Plausibly Alleges CVS Health Is a Proper Defendant 64
2. Ellsworth Adequately Alleges CVS Pharmacy Is a Proper Defendant 65

CONCLUSION 67

CERTIFICATE OF SERVICE 68

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Anjelino v. N.Y. Times Co.,
200 F.3d 73 (3d Cir. 1999).....15, 18

Anthony v. Council,
316 F.3d 412 (3d Cir. 2003).....49

In re Asbestos Prods. Liab. Litig. (No. VI),
822 F.3d 125 (3d Cir. 2016).....15

Ashcroft v. Iqbal,
556 U.S. 662 (2009).....15

Bailey v. Viacom, Inc.,
No. CIV.A. 4-607, 2009 WL 185957 (W.D. Pa. Jan. 23, 2009).....15

Barry Wright Corp. v. ITT Grinnell Corp.,
724 F.2d 227 (1st Cir. 1983).....18

Blanyar v. Genova Prods. Inc.,
861 F.3d 426 (3d Cir. 2017).....15

In re Burlington Coat Factory Sec. Litig.,
114 F.3d 1410 (3d Cir. 1997).....11

Christidis v. First Pa. Mortg. Tr.,
717 F.2d 96 (3d Cir. 1983).....16

Foglia v. Renal Ventures Mgmt., LLC,
754 F.3d 153 (3d Cir. 2014).....16, 32, 34, 38, 40

Franchitti v. Cognizant Tech. Sols. Corp.,
555 F. Supp. 3d 63 (D.N.J. 2021).....60

Halo Elecs., Inc. v. Pulse Elecs., Inc.,
579 U.S. 93 (2016).....29

Jackson v. Se. Pa. Transp. Auth.,
No. CIV.A.08-4572, 2009 WL 637460 (E.D. Pa. Mar. 10, 2009).....30

Kronfeld v. First Jersey Nat'l Bank,
638 F.Supp. 1454 (D.N.J. 1986).....16

In re Nat'l Prescription Opiate Litig.,
No. 18-OP-45032, 2022 WL 671219 (N.D. Ohio Mar. 7, 2022).....25

Pryor v. Nat'l Collegiate Athletic Ass'n.,
288 F.3d 548 (3d Cir. 2002).....30

Purcell v. Gilead Scis., Inc.,
439 F. Supp. 3d 388 (E.D. Pa. 2020).....43

Rose v. Bartle,
871 F.2d 331 (3d Cir. 1989).....55

Safeco Ins. Co. of Am. v. Burr,
551 U.S. 47 (2007).....29, 30

Sturgeon v. Pharmerica Corp.,
438 F. Supp. 3d 246 (E.D. Pa. 2020).....10, 24, 39, 44

United States ex rel. Bassan v. Omnicare, Inc.,
No. 1:15-CV- 4179 (CM), 2021 WL 1063784 (S.D.N.Y. Mar. 19, 2021).....65

United States ex rel. Boise v. Cephalon, Inc.,
Civ. No. 08-287, 2015 WL 1724572 (E.D. Pa. Apr. 15, 2015).....57

United States ex rel. Boise v. Cephalon, Inc.,
No. 08-287, 2015 WL 4461793 (E.D. Pa. July 21, 2015).....54

United States ex rel. Budike v. Peco Energy,
No. 07-4147, 2013 WL 5890650 (E.D. Pa. Nov. 4, 2013).....55

United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.,
839 F.3d 242 (3d Cir. 2016).....53

United States ex rel. D'Cunha v. Luketich,
No. CV 19-495, 2022 WL 2359417 (W.D. Pa. June 30, 2022).....5

United States. ex rel. Escobar v. Univ. Health Servs., Inc.,
842 F.3d 103 (1st Cir. 2016).....28

United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.,
38 F. Supp. 3d 398 (S.D.N.Y. 2014).....33, 60

United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh,
718 Fed. App'x 101 (3d Cir. 2018).....60, 63

United States ex rel. Galmines v. Novartis Pharms. Corp.,
No. CIV.A. 06-3213, 2013 WL 2649704 (E.D. Pa. June 13, 2013).....42

United States ex rel. Garbe v. Kmart Corp.,
824 F.3d 632 (7th Cir. 2016) 29

United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.,
96 F. Supp. 3d 504 (E.D. Pa. 2015) 57

United States ex rel. Hendow v. Univ. of Phoenix,
461 F.3d 1166 (9th Cir. 2006) 41

United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union No. 98 v. Farfield Co.,
5 F.4th 315 (3d Cir. 2021) 27, 28

United States ex rel. Judd v. Quest Diagnostics Inc.,
638 F. App'x 162 (3d Cir. 2015) 62

United States ex rel. Mateski v. Raytheon Co.,
816 F.3d 565 (9th Cir. 2016) 60

United States ex rel. Miller v. Weston Educ., Inc.,
840 F.3d 494 (8th Cir. 2016) 41

United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC,
812 F.3d 294 (3d Cir. 2016).....57, 61, 62

United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.,
No. 05-2927, 2010 WL 5466043 (D.N.J. Dec. 30, 2010).....55

United States ex rel. Polansky v. Exec. Health Res., Inc.,
196 F. Supp. 3d 477 (E.D. Pa. 2016) 64, 65

United States ex rel. Prather. v. Brookdale Senior Living Cmtys., Inc.,
838 F.3d 750 (6th Cir. 2016) 53

United States ex rel. Prose v. Molina Healthcare of Ill., Inc.,
17 F.4th 732 (7th Cir. 2021) 29

United States ex rel. Schmidt v. Zimmer, Inc.,
386 F.3d 235 (3d Cir. 2004).....42, 64, 65, 66

United States ex rel. Silver v. Omnicare, Inc.,
903 F.3d 78 (3d Cir. 2018).....58

United States ex rel. Sirls v. Kindred Healthcare, Inc.,
469 F. Supp. 3d 431 (E.D. Pa. 2020) 17, 65

United States ex rel. Spay v. CVS Caremark Corp.,
913 F. Supp. 2d 125 (E.D. Pa. 2012) 50

United States ex rel. Stepe v. RS Compounding LLC,
325 F.R.D. 699 (M.D. Fla. 2017).....29

United States ex rel. Streck v. Bristol-Myers Squibb Co.,
370 F. Supp. 3d 491 (E.D. Pa. 2019).....31

United States ex rel. Suarez v. AbbVie, Inc.,
503 F. Supp. 3d 711 (N.D. Ill. 2020).....49

United States ex rel. Travis v. Gilead Scis., Inc.,
No. CV 17-1183, 2022 WL 991382 (E.D. Pa. Apr. 1, 2022).....10, 24, 44, 56

United States ex rel. Wilkins v. United Health Grp., Inc.,
659 F.3d 295 (3d Cir. 2011).....21, 50

United States ex rel. Wood v. Allergan, Inc.,
246 F. Supp. 3d 772 (S.D.N.Y. 2017).....49

United States v. Beatrice Foods Co.,
330 F. Supp. 577 (D. Utah 1971).....17

United States v. Caminos,
770 F.2d 361 (3d Cir. 1985).....30

United States v. Planned Parenthood Fed'n of Am. Inc.,
No. 2:21-CV-022-Z, 2022 WL 1290907 (N.D. Tex. Apr. 29, 2022).....65

Universal Health Servs., Inc. v. United States ex rel. Escobar,
579 U.S. 176 (2016).....22, 27, 28

Victaulic Co. v. Tieman,
499 F.3d 227 (3d Cir. 2007).....26

ZF Meritor, LLC v. Eaton Corp.,
696 F.3d 254 (3d Cir. 2012).....18

State Cases

Correa v. Schoeck,
98 N.E.3d 191 (Mass. 2018).....25

Federal Statutes

1 U.S.C. § 1.....61

15 U.S.C. § 1.....16

15 U.S.C. § 15a.....16

31 U.S.C § 3729(a)(1)(A) 4, 55

31 U.S.C. § 3729(a)(1)(C) 4, 54

31 U.S.C. § 3729(a)(1)(G) 4, 53

31 U.S.C. § 3729(b) 4

31 U.S.C. § 3729(b)(1)(A)(i) 30

31 U.S.C. § 3729(b)(1)(A)(ii) 30

31 U.S.C. § 3729(b)(3) 54

31 U.S.C. § 3729(b)(4) 5, 27

31 U.S.C. § 3729(c) 4

31 U.S.C. § 3730(e)(4)(A) 57, 62

31 U.S.C. § 3730(e)(4)(B) 61

42 U.S.C. § 1395w-101(a)(2) 48

42 U.S.C. § 1395w-111(i)(1) 21

Medicare Prescription Drug, Improvement, and Modernization Act,
Pub. L. 108-173, 117 Stat. 2066 (Dec. 8, 2003) 5

State Statutes

Minn. Stat. § 151.21(5) 24

N.J. Stat. § 24:6E-7 25

Nev. Rev. Stat. § 639.2583(7)(c)(1) 24

Nev. Rev. Stat. § 639.2583(7)(c)(2) 24

Tenn. Code § 53-10-205(d)(1) 25

Wis. Stat. § 450.13(1s) 25

Rules

Fed. R. Civ. P. 9(b) 15

Fed. R. Civ. P. 12(b)(6) 15

Regulations

42 C.F.R. § 423.100 ..... 12, 24, 28, 45

42 C.F.R. § 423.104 28

42 C.F.R. § 423.128(a)(2) 44

42 C.F.R. § 423.128(b)(2)(iii) 44

42 C.F.R. § 423.132 45

42 C.F.R. § 423.505(k)(3) 33

42 C.F.R. § 423.578(a) 24, 45

42 C.F.R. § 423.578(b) 24, 45

42 C.F.R. § 423.578(b)(5)(i) 6, 36

Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194 (Jan. 28, 2005) 45

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22072 (Apr. 12, 2012) 12

Contract Year 2022 Policy and Technical Changes to the Medicare Program, 86 Fed. Reg. 5864 (Jan. 19, 2021) 44

Executive & Congressional Publications

CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data* (2006) 10, 11

CMS, *Medicare Marketing Guidelines* (2018) 44

CMS, *Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements* (2016) 24, 45

U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs* (2019) 38, 39

Drug Pricing in America: A Prescription for Change, Part III: Hearing before the S. Comm. on Fin., 116th Cong. 415 (2019) 59

Websites

CMS, *Exceptions*, https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions 6

CMS, *What Medicare Part D drug plans cover*, https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover 6

FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority* (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority 52

Other Authorities

Joel Hesch, *Understanding the Revised Reverse False Claims Provision of the False Claims Act and Why No Proof of a False Claim is Required*, 53 UIC J. Marshall L. Rev. 461 (2021) 54

INTRODUCTION

This case arises out of a False Claims Act suit to hold Defendants, various CVS Health entities, responsible for anticompetitive and fraudulent conduct in administering a Medicare Part D plan sponsored by SilverScript. Defendants, in exchange for rebate payments from manufacturers of fifteen brand-name drugs, agreed to give those brand-name drugs an effective monopoly by precluding the substantially cheaper generic equivalents of those drugs from competing in the SilverScript Medicare Part D marketplace. Defendants accomplished their plan by misleading SilverScript's plan beneficiaries about the availability and cost of generic drugs; blocking access to certain generic drugs by improperly denying formulary exceptions for those drugs as a matter of course; and instructing CVS pharmacies not to stock certain generic drugs. Defendants then attempted to conceal that fraudulent conduct through, *inter alia*, improper coding of Medicare Part D claims and inadequate compliance programs. As a result of Defendants' fraudulent scheme, Medicare Part D beneficiaries on SilverScript's plan were effectively denied their rights under Medicare Part D to make informed decisions about their prescription drug benefits and to request a generic drug rather than a brand-name drug, resulting in greater costs for both SilverScript beneficiaries and the United States Government.

In the face of these allegations, Defendants urge dismissal solely on the ground that "[n]either Congress nor CMS . . . constricts plan sponsors' discretion to prefer brand drugs on their formularies." Br. at 1. But that is not in dispute. Relator does not challenge SilverScript's preference for brand-name drugs on its formulary or contend that SilverScript's exclusion of generic drugs from its formulary, standing alone, is fraudulent.

Relator's action instead is premised on Defendants' specific fraudulent actions in implementing SilverScript's plan, which involved deceiving and misleading plan beneficiaries and

blocking generic prescription drugs from competing against the fifteen identified brand-name drugs. Defendants do not seriously deny those substantive allegations. Instead, Defendants suggest (Br. at 3) that those allegations are irrelevant "because the brand drug is precisely what the government has approved paying for." But Congress, in permitting plan sponsors to design their own formulary (including formularies preferring brand-name drugs) did not authorize Defendants to engage in anticompetitive conduct to thwart market competition, to mislead beneficiaries about the costs of prescription drugs (including generic equivalents), to violate state laws requiring substitution of generic drugs, to conspire to ensure that generic drugs were unavailable at the pharmacy so that beneficiaries could not have obtained a generic drug even if they otherwise would have been entitled to that drug, or to conceal such actions. Defendants' conduct thus effectively denied SilverScript beneficiaries the option of seeking a formulary exception for a cheaper generic drug, which, absent Defendants' actions, beneficiaries would have had every incentive to do. Not only that, SilverScript would have been required to grant formulary exceptions for cheaper generic drugs because, absent such exceptions, beneficiaries would have suffered adverse effects in having to pay greater out-of-pocket costs for brand-name drugs. Defendants' suggestion that the United States Government would have agreed to pay for a more expensive brand-name drug, regardless of whether a Medicare Part D beneficiary sought and obtained a generic substitute, simply defies belief.

Defendants also ask the Court to dismiss this action pursuant to the public disclosure bar. But Defendants fail to cite any public disclosures that reveal the specific allegations of Defendants' fraud: Defendants' misleading statements to beneficiaries about the costs and availability of generic drugs; blanket refusals for formulary exceptions for certain generics; and instructions to CVS Pharmacies to not stock certain generics. In any event, even if the allegations of fraud had

been publicly disclosed, Relator, through the personal knowledge and experience of one of its partners—a former CVS Health executive—has contributed information, distinct from what was publicly disclosed, that significantly adds to "the who, what, when, where and how" of the alleged fraud, such that Relator qualifies as an original source.

Finally, this Court should reject Defendants' argument that neither CVS Health nor CVS Pharmacies is a proper party because neither was purportedly directly involved in the submission of false claims to the Government. Liability under the False Claims Act does not turn on whether either party directly submitted false claims, but on whether they were actively involved in the fraudulent scheme. Relator alleges how the Executive Committee, a standing committee of CVS Health's Board, controlled the scheme at each step, ensuring an "enterprise-wide benefit," knowing that beneficiaries and the Government would be harmed. Likewise, Relator alleges that the CVS Pharmacies were directly involved in the scheme by refusing to stock certain generics, by failing to follow state generic substitution laws, and by miscoding prescriptions submitted to the Government.

For all of these reasons, the Court should deny Defendants' motion to dismiss.

STATEMENT OF FACTS

Plaintiff-Relator, Ellsworth Associates, LLP ("Ellsworth" or "Relator"), is a Delaware limited liability partnership. One of its partners, Alexandra Miller, was employed by CVS Health for 19 years, eventually being promoted to a senior executive position. She has extensive personal knowledge and experience regarding the alleged misconduct, including personal contact with the CVS Health employees and executives who have committed the alleged violations of law.

Ellsworth alleges that CVS Health and its subsidiaries[1] (collectively, "Defendants") caused the submission of false claims; made, used, or caused to be made or used, false records or statements material to false or fraudulent claims; knowingly made, used, or caused to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government; and conspired to do the same, all in violation of the False Claims Act ("FCA"). 31 U.S.C. § 3729(a)(1)(A)-(C), (G).

A. The False Claims Act

The FCA prohibits "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval, 31 U.S.C § 3729(a)(1)(A); "knowingly" making, using, or causing to be used or made a false record or statement material to a false or fraudulent claim, *id.* § 3729(a)(1)(B); "knowingly mak[ing], us[ing], or caus[ing] to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government," *id.* ¶ 3729(a)(1)(G); and conspiring to commit a violation of the provisions of the FCA, *id.* § 3729(a)(1)(C).

"[K]nowing" and "knowingly" mean that a person: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b). A "claim" includes "any request or demand . . . for money or property which is made to a contractor, grantee, or other recipient if the United States government provides any portion of the money or property . . . , or if the government will reimburse . . . any portion of the money or property." 31 U.S.C. §

[1] The CVS Health subsidiaries are SilverScript Insurance Company, CVS Caremark Corporation, and CVS Pharmacy, Inc. Defendants argue (Br. at 9 n.3) that, rather than CVS Caremark Corporation, the proper pharmacy benefit management ("PBM") company should be CVS Caremark Part D Services, L.L.C. The Parties have met and conferred and have agreed they will resolve this issue during discovery.

3729(c). Because Medicare claims are paid or reimbursed, at least in part, by the United States Government, they may give rise to liability under the FCA. *See, e.g.*, *United States ex rel. D'Cunha v. Luketich*, No. CV 19-495, 2022 WL 2359417, at *2 (W.D. Pa. June 30, 2022) ("[B]y submitting claims to Medicare and other Government Health Benefit Programs, Defendants presented claims for payment to the Government."). A false statement or record is "material" if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

B. Medicare Part D

Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly, end stage renal disease ("ESRD") and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare & Medicaid Services ("CMS"). Medicare Part D, one of four parts of Medicare, is a voluntary prescription drug benefit program, established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066 (Dec. 8, 2003). It became effective January 1, 2006. Second Amended Complaint (hereinafter "SAC") ¶ 60.

Medicare Part D is based on a private market model in which CMS contracts with private entities, known as "Sponsors," to administer prescription drug plans or "PDPs." SAC ¶¶ 61-62. For the Medicare Part D private model to operate successfully, "[t]he United States relies on the interactions of private entities—drug manufacturers, health plans and pharmaceutical benefit managers (PBMs)—to achieve value by negotiating prices, operating formularies and implementing other benefit management strategies." *Id*.

A Sponsor's Part D plan must cover a wide range of prescription drugs that Medicare beneficiaries require. A plan's list of covered drugs is called a formulary. Plans usually include

both brand-name and generic drugs. The drugs on a plan's formulary are generally placed into different levels, called "tiers," which determine their costs. If a certain drug is not on a plan's formulary, a beneficiary has the right to request a formulary exception to obtain the drug. *See* CMS, *What Medicare Part D drug plans cover*, https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover (last visited Sept. 22, 2022).

A formulary exception request is a type of coverage determination under which a beneficiary (or the beneficiary's representative) can request a Part D drug that is not included on a plan sponsor's formulary. *See generally* SAC ¶¶ 120-23.[2] The Sponsor is required to grant a formulary exception and cover the requested drug if the formulary drug either "would not be as effective" for the beneficiary as the requested drug or "would have adverse effects" for the beneficiary. 42 C.F.R. § 423.578(b)(5)(i).

Medicare Part D beneficiaries' coverage varies over the course of a plan year:

a) Deductible: Beneficiaries do not receive any benefits under Medicare Part D until their out-of-pocket costs meet a modest deductible amount (up to $415 for 2019).[3]

b) Initial Coverage Limits ("ICL"): Once a beneficiary meets his or her deductible, he or she receives prescription drug benefits up to an annual cap ($3,820 for 2019).

c) Coverage Gap (the "Donut Hole"): After the beneficiary reaches the annual cap of

[2] *See also* CMS, *Exceptions*, https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions (last visited Sept. 22, 2022).

[3] The Part D Low-Income Subsidy ("LIS") program provides premium and cost-sharing assistance for Part D enrollees with low incomes (less than 150% of poverty, or $20,385 for individuals/$27,465 for married couples in 2022) and modest assets (less than $14,010 for individuals/$27,950 for couples in 2022. LIS 1, 2, and 3 beneficiaries do not have a deductible, and LIS 4 beneficiaries have a reduced deductible. *See* Kaiser Family Foundation, available at https://www.kff.org/medicare/stateindicator/number-of-low-income-subsidy-lis-enrollees/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

the initial coverage, the beneficiary pays out of pocket until his or her total out-of-pocket costs reach a "catastrophic coverage" threshold ($5,100 for 2019).

d) Catastrophic Coverage: After the beneficiary meets the "catastrophic coverage" threshold, the beneficiary again receives prescription drug benefits under a reinsurance scheme, in which the United States Treasury pays 80% of costs, the Sponsor pays 15%, and the beneficiary pays 5%.

SAC ¶ 74.

When a pharmacy dispenses a drug to a Medicare Part D beneficiary, it submits an electronic claim to the beneficiary's Sponsor to receive reimbursement for the costs not paid by the beneficiary. The Sponsor (or its PBM) then submits a Prescription Drug Event ("PDE") record to CMS that reflects that a drug has been purchased and dispensed. SAC ¶ 69. The PDE is an electronically created document that includes multiple transactional and calculated fields about the specific drug dispensed, to include the amount paid by the beneficiary to the pharmacy. *Id.* CMS uses the PDE at the end of the payment year to reconcile its advance payments to the Sponsor with the Sponsor's actual costs. *Id.* ¶ 70.

Medicare Part D imposes a host of regulatory requirements on Sponsors who offer prescription drug plans, the most significant of which are summarized below.

1. Sponsors Must Certify the Accuracy, Completeness, and Truthfulness of Claims Data Submitted to CMS

Sponsors subcontract with multiple entities to provide benefits to Part D beneficiaries, including pharmacy benefits managers or "PBMs," which administer the Sponsor's formulary and pharmacy benefits and arrange for pharmacies to participate in the plan's network. SAC ¶ 71. "As a condition for receiving its monthly payment from CMS, a PDP Sponsor must certify as to the accuracy, completeness, and truthfulness of all data related to the payment, which may include

enrollment information, claims data, bid submission data, and any other data specified by CMS." *Id.* ¶ 168. The same requirement applies to a Sponsor's subcontractors, such as a PBM. *Id.*

2. Part D Sponsors Must Have a Robust Compliance Program.

Sponsors must annually agree in writing to comply with CMS regulations. *Id.* ¶ 78-79, 209. Among other obligations, Sponsors are required to (i) maintain a compliance program to ensure the integrity of their payment data; (ii) annually attest to the accuracy and truthfulness of that data; and (iii) "comply with . . . Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law [and] the False Claims Act (31 USC §§ 3729 et seq.)." *Id.*

An effective compliance program is a prerequisite for a Sponsor to obtain, and retain, payments under Part D. *Id.* ¶ 81-83. A fundamental part of any compliance program is ensuring that the Sponsor acts ethically and honestly: a Sponsor must "[a]ct fairly and honestly, [a]dhere to high ethical standards in all [it does], [c]omply with all applicable laws, regulations, and CMS requirements, [and r]eport suspected violations." *Id.* ¶ 86. Non-compliant conduct is conduct that does "not conform to the law, Federal health care program requirements, or an organization's ethical and business policies." *Id.* ¶ 87. CMS has identified certain types of conduct that pose a high risk of noncompliance: appeals and grievance review; ethics; and pharmacy, formulary, and benefit administration. *Id.*

3. Part D Plans Must Provide Beneficiaries the Right to Seek Coverage Determinations and File Grievances

Medicare Part D provides beneficiaries with certain protections. For example, CMS guidance states that "[n]o matter how you get your Medicare, you have certain rights and protections designed to [p]rotect you when you get health care[;] [m]ake sure you get the health care services that the law says you can get[;] and [p]rotect you against unethical practices." SAC

¶ 100. These protections include:

- the right to "[g]et clear and simple information about Medicare to help you make health care decisions, including [w]hat's covered[;] [w]hat Medicare pays[;] [h]ow much you have to pay[;] [and w]hat to do if you want to file a complaint or an appeal." *Id.* ¶ 101.
- the right to "[g]et a coverage decision or coverage information from your plan before getting services." *Id.* ¶ 103.
- the right to "[r]equest an appeal to resolve differences with your plan. You have the right to ask your plan to provide or pay for an item or service you think should be covered, provided, or continued. If your plan denies your request, you have the right to appeal that decision." *Id.* ¶ 102.

These requirements apply to Sponsors like SilverScript that offer prescription drug benefits directly to beneficiaries. *Id.* ¶ 104.

Coverage determinations (including whether a beneficiary may receive a formulary exception) and grievance procedures serve as a "safety net" to deter improper formulary administration and ensure a beneficiary's access to medically necessary or life-sustaining services or drugs. *Id.* ¶ 105. Improper processing of grievances and coverage determinations denies beneficiaries due process and appeal rights and may delay a beneficiary's access to medically necessary, often life-sustaining, services or drugs. *Id.* ¶ 106. CMS may impose sanctions (such as suspension of enrollment and marketing), civil monetary penalties, or terminate Sponsors who have improperly denied medically necessary items and services. *Id.* ¶ 108.

4. Sponsors Must Advise Beneficiaries of the Cost Differential for the Lowest-Price Generic Alternative.

Medicare requires Sponsors to have a "cost-effective drug utilization management program," which includes using "incentives to reduce costs when medically appropriate, such as

through the use of multiple source drugs."[4] SAC ¶ 140. Thus, Medicare explicitly recognizes that generic drugs are one way to lower costs. *Id.*

Medicare Part D also requires a Sponsor to ensure that its network pharmacies advise beneficiaries of any price differential between the drug dispensed and the lowest-priced generic that is both therapeutically equivalent and bioequivalent, and available at the pharmacy. *Id.* ¶ 141. This disclosure requirement is not limited to when the beneficiary specifically requests such pricing information, or to when the prescriber has instructed "Do No Substitute" (*i.e.,* DAW 2). *Id.* ¶ 144.

5. Sponsors Must Submit Accurate DAW Coding as Part of Each Claim

Sponsors are required to submit data, referred to as PDEs, for each prescription filled under the plan. SAC ¶ 151. PDE data are used, in part, to validate claims, monitor quality, and make year-end risk corridor calculations. *Id*. When pharmacies dispense drugs to Medicare Part D beneficiaries, pharmacies submit claims electronically to the beneficiaries' Sponsor (often via a PBM), which includes the ingredient cost (the cost of the drug itself), any dispensing fee, any sales or similar taxes paid, any payments made by the beneficiary, and any rebates received from the drug's manufacturer or distributor. *Id.* ¶ 152.

PDE records contain 37 data elements: 17 defined by CMS and 20 defined by the National Council for Prescription Drug Programs ("NCPDP"). CMS, *Instructions: Requirements for Submitting Prescription Drug Event Data* 9 (2006), *available at* https://tinyurl.com/dxau5pf6.[5]

[4] "Multiple-source drugs" are drugs for which there is a brand-name and an approved generic alternative.

[5] The Court may take judicial notice of this document because it is a "readily available guidance document[] whose accuracy" cannot be questioned. *See United States ex rel. Travis v. Gilead Scis., Inc.*, No. 17-1183, 2022 WL 991382, at *7 (E.D. Pa. Apr. 1, 2022). Moreover, "information found on government websites is widely considered both self-authenticating and subject to judicial notice." *Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d 246, 259 (E.D. Pa. 2020). In addition, "a 'document integral to or explicitly relied upon in the complaint' may be considered" on a motion

The Sponsor is responsible for the submission of accurate PDE data to CMS and the submission of such data is "a condition of payment." *Id.* ("For each dispensing event, the plan must submit a prescription drug event or PDE record."); *id.* at 5 ("As a condition of payment, all Part D plans must submit data and information necessary for CMS to carry out payment provisions[.]").

Field 18, particularly relevant here, "indicate[s] the prescriber's instruction regarding substitution of generic equivalents or order to dispense the specific product written." *Id.* at 13. Ten numbers (0-9), called DAW codes (short for "dispense as written"), may be entered into Field 18 to indicate whether a generic drug was substituted for a brand-name and, if not, why not. While Code 0 is the "default," the instructions make clear that, for "a multi-source branded product with available generic(s), *DAW 0 is not appropriate, and may result in a reject*." SAC ¶ 161.

The DAW code chosen by the pharmacy (and which is then certified as accurate by the Sponsor) is determined by several variables, such as the prescriber's instructions, the patient's request for a brand-name or generic drug, state pharmacy law, and whether there are different versions of the prescribed drug (*e.g.*, if there is a generic and a brand-name version). If a pharmacy dispenses a brand-name multi-source drug (a drug for which there is a brand-name and an approved generic from another labeler), the DAW code must supply the basis for the pharmacy's decision not to substitute a generic. CMS recognizes that "excessive use of certain DAW codes may raise red flags from an audit perspective, especially the use of DAW 1 on multi-source products. Review acceptable use of DAW 1 and DAW 9 codes with staff and emphasize appropriate documentation procedures."[6] *Id.* ¶ 165.

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to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). *See* SAC ¶ 151-57 (citing document).

[6] DAW code 1 indicates "substitution not allowed by prescriber," and DAW code 9 indicates "substitution allowed by prescriber but plan requests brand." SAC ¶ 159.

Sponsors must certify to CMS that the PDE information is accurate, complete, and truthful. *Id.* ¶ 168. CMS has specifically identified the "inappropriate use of dispense as written ('DAW') codes" as an example of potential fraud, waste, and abuse that may violate federal law. *Id.* ¶ 174.

6. Sponsors Must Comply with State Mandatory Generic Substitution Laws

"A Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." SAC ¶ 191. To be considered "valid," a prescription must "compl[y] with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100. "Since the inception of the Part D Program, [CMS] ha[s] consistently maintained that drugs cannot be eligible for Part D coverage unless they are dispensed upon prescriptions that are valid under applicable State law." *Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes*, 77 Fed. Reg. 22072, 22139 (Apr. 12, 2012). This means that "[s]tate law applies in determining what constitutes a valid prescription and that Part D benefits should be available only for otherwise covered drugs that are dispensed upon a valid prescription." *Id.* Those participating in Medicare Part D "need to consult State law to determine whether a prescription is valid." *Id.*

Seventeen jurisdictions require that generic drugs must be substituted for brand-name drugs for all beneficiaries, including Medicare Part D, when the generic drug is cheaper for the beneficiary.[7] *See* Appendix: Generic Substitution Laws. These requirements apply regardless of whether the generic drug is on the Sponsor's formulary. A Sponsor (or its PBM) that submits PDE records to Medicare when it knows (or should have known) that its network pharmacies are not

[7] The SAC inadvertently identified Maryland as a mandatory-substitution jurisdiction when it is not. The SAC also inadvertently identified Indiana as a permissive-substitution jurisdiction when, in fact, it is a mandatory-substitution jurisdiction.

complying with the mandatory substitution law in that state has knowingly submitted (or caused to be submitted) false PDE records or statements. SAC ¶ 197.

C. Defendants' Fraudulent Scheme

Since at least June 22, 2015, CVS Caremark's rebate agreements with various drug manufacturers required it to block access to generic versions of fifteen brand-name drugs. These brand-name drugs are referred to in the SAC as "Single Source Generic/Do Not Substitute" ("SSG/DNS") drugs: Copaxone (manufactured by Teva), Exelon (Novartis), Voltaren Gel (Endo), Invega (Janssen), Asacol HD (Allergan), Xopenex HFA (Sunovion), Renvela Packets (Sanofi), Renvela Tablets (Sanofi), Istalol (Bausch & Lomb), Harvoni (Gilead), Epclusa (Gilead), Ventolin HFA (GSK), Canasa Rectal Suppository (Allergan), Advair Diskus (GSK), and Suboxone Sublingual Film (Indivior). SAC ¶¶ 5, 320. Defendants, in exchange for rebates received for these brand-name drugs, agreed to assist drug manufacturers in stifling competition from the generic versions of these drugs, thereby significantly increasing costs for SilverScript beneficiaries and the Government by effectively eliminating the option of substituting a cheaper generic drug for a brand-name drug. *Id.* ¶¶ 3, 4, 6, 252, 289, 299, 348. The inability to obtain cheaper generic drugs often drove beneficiaries into the Catastrophic Coverage Stage of their Medicare Part D benefits, where many beneficiaries could not afford the copayments on the brand-name drugs. *Id.* ¶ 350.

The SAC details how the rebate deals cut by CVS Caremark rendered Defendants complicit in the drug manufacturers' efforts to block competition posed by generic drugs. *Id.* ¶¶ 289, 319. As such, Defendants have aided and abetted the drug manufacturers in competing not on the basis of innovation, but rather based on their ability to limit competition by obstructing access to generic drugs. *Id.* ¶¶ 6, 425.

Ellsworth alleges that the rebate agreements required Defendants' call center Customer Care Representatives ("CCRs") to provide intentionally misleading information to SilverScript

beneficiaries about access to cheaper generic drugs and, more troublingly, provide intentionally deceptive statements to beneficiaries that the brand-name drugs at issue would be cheaper than the generics. *Id.* ¶¶ 378, 382, 386, 407, 413, 435, 438, 442, 469, 473, 475, 478, 482, 503, 506, 510, 513, 516, 520, 625, 628, 631, 647, 650, 653, 686, 690. Those statements sought to discourage SilverScript beneficiaries from requesting formulary exceptions for generic drugs because Defendants knew that, if beneficiaries requested such formulary exceptions, Defendants would have no legitimate basis for denying them. *Id.* As a further backstop, however, Defendants ensured that the costlier brand-name drug would ultimately be dispensed, regardless of the beneficiary's preference, by requiring CVS Pharmacies not to stock the cheaper generic drugs, even though such action, in some states, precluded the pharmacies from complying with state mandatory generic substitution laws. *Id.* ¶ 12. At its core, Defendants' scheme involved a calculated and widespread campaign of misinformation and deception to SilverScript beneficiaries. *Id.* ¶ 13. In doing so, CVS Health and its subsidiaries denied Part D beneficiaries access to cheaper generic drugs by withholding information about generic options, deceiving those who sought generic pricing information to discourage beneficiaries from requesting formulary exceptions, and denying formulary exceptions to those who nevertheless sought them. *Id.* ¶ 14.

Realizing there was even more profit to be made if beneficiaries' access to cheaper generic drugs were eliminated entirely, the SAC specifically alleges that the rebate deal between CVS Caremark and Gilead for two brand-name drugs, Harvoni and Epclusa, required the blanket denial of all formulary exceptions for those expensive drugs, thus driving elderly, ESRD, and disabled beneficiaries into the Donut Hole and Catastrophic Coverage Stages of their Part D benefits, where they and the Government faced substantial out-of-pocket costs. *Id.* ¶¶ 14, 278, 541, 557, 575, 598. In addition, the SAC alleges that, under CVS Caremark's rebate agreements with Gilead and GSK,

CVS Pharmacies were required to stop stocking the generic versions of Gilead's Harvoni and Epclusa, and GSK's Advair Diskus and Ventolin HFA. *Id.* ¶¶ 15, 278, 317, 350, 498, 528, 622-23.

LEGAL STANDARD

When considering a dismissal pursuant to Rule 12(b)(6), the Court "must accept as true all plausible facts alleged in [the plaintiff's] complaint and draw all reasonable inferences in her favor," *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 131 (3d Cir. 2016), "construe[ing] the complaint in the light most favorable to [her]," *Blanyar v. Genova Prods. Inc.*, 861 F.3d 426, 431 (3d Cir. 2017) (quoting *Fleisher v. Standard Ins. Co.*, 679 F.3d 116, 120 (3d Cir. 2012)); *see Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("[T]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007))). A district court may not "weigh[] the credibility of the parties' positions on" "a question of disputed material fact[]" at the motion to dismiss stage, but rather "should . . . le[ave] such considerations to a jury." *Anjelino v. N.Y. Times Co.*, 200 F.3d 73, 97 (3d Cir. 1999).

Although Rule 9(b) requires a plaintiff to plead fraud "with particularity," a plaintiff is not required to "plead the 'date, place or time' of the fraud, so long as [plaintiff] use[s] 'an alternative means of injecting precision and some measure of substantiation into [her] allegations.'" *Bailey v. Viacom, Inc.*, No. CIV.A. 4-607, 2009 WL 185957, *1 (W.D. Pa. Jan. 23, 2009) (quoting *Seville Indus. Machinery v. Southmost Machinery*, 742 F.2d 786, 791 (3d Cir. 1984)), *abrogated in part on other grounds by Rotella v. Wood*, 528 U.S. 549 (2000). "In applying the first sentence of Rule 9(b) courts must be sensitive to the fact that its application, prior to discovery, may permit

sophisticated defrauders to successfully conceal the details of their fraud." *Christidis v. First Pa. Mortg. Tr.*, 717 F.2d 96, 99-100 (3d Cir. 1983).

In the FCA context, a plaintiff must provide only "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156-57 (3d Cir. 2014) (internal quotation marks omitted). A plaintiff need not show "the exact content of the false claims in question," as "requiring this sort of detail at the pleading stage would be one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Id.* at 156 (internal quotation marks and citation omitted). Less specificity is required where the defendant is the only party with "access to the documents that could easily prove the claim one way or another." *See id.* at 158. In addition, courts in this Circuit have held that "when the transactions are numerous and take place over an extended period of time, less specificity in pleading fraud is required." *E.g.*, *Kronfeld v. First Jersey Nat'l Bank*, 638 F. Supp. 1454, 1465 (D.N.J. 1986).

ARGUMENT

I. ELLSWORTH HAS ADEQUATELY ALLEGED VIOLATIONS OF THE FALSE CLAIMS ACT.

A. Defendants Engaged in Anticompetitive Conduct That Defrauded the Government.

The Clayton Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of [interstate] trade or commerce." 15 U.S.C. § 1. Section 4A of the Clayton Act allows the Government to recover treble damages for injury "by reason of anything forbidden in the antitrust laws" when the Government itself is the victim. 15 U.S.C. § 15a.

Anticompetitive conduct in violation of the antitrust laws may be the predicate for a False

Claims Act action. For example, in 2019 the United States entered into a $1.4 billion settlement with Reckitt Benckiser Group LLC, the maker of one of the brand-name drugs at issue here, Suboxone, for alleged anticompetitive conduct that harmed "federal healthcare programs" and thereby violated the False Claims Act. *See* Non-Prosecution Agreement, *United States v. $647,000,000 in U.S. Currency*, No. 1:19-cv-27 (W.D. Va. June 11, 2019), ECF 2-1 at 8-9, *available at* https://www.justice.gov/opa/press-release/file/1181826/download[8]; *see also United States v. Beatrice Foods Co.*, 330 F. Supp. 577, 579 (D. Utah 1971) (permitting FCA suit premised on antitrust violations to proceed).[9]

"Medicare Part D relies on fair competition in private market negotiations between Part D plans, PBMs, pharmacies and drug makers to ensure that the benefits offered provide quality drugs at affordable prices." SAC ¶ 2. "Policymakers envisioned the Part D program would rely on private plan sponsors that bear insurance risk competing in the marketplace to provide attractive benefit packages and drug prices that are fairly negotiated in order to make these often lifesaving medications more affordable." *Id.* ¶ 63. As relevant to this case, federal antitrust laws, including the Clayton Act, prohibit companies from "engag[ing] in deceptive business practices that

[8] "[T]he Court may take judicial notice of . . . court filings that are publicly filed on the docket of a district court." *United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 469 F. Supp. 3d 431, 439 n.3 (E.D. Pa. 2020).

[9] *See also* Press Release, U.S. Dep't of Justice, *DOJ Agrees to Civil Settlement with Additional Firm Involved in Bid Rigging and Fraud Targeting Defense Department Fuel Supply Contracts for U.S. Military Bases in South Korea* (July 11, 2019), https://www.justice.gov/opa/pr/doj-agrees-civil-settlement-additional-firm-involved-bid-rigging-and-fraud-targeting-defense (sixth settlement in series of fuel price-fixing cases); Press Release, U.S. Dep't of Justice, *Pharmaceutical Companies Pay Over $400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs* (Oct. 1, 2021), https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability ($400 million settlement involving third, fourth, and fifth price fixing claims).

unreasonably deprive consumers of the benefits of competition" and from "shar[ing] competitively sensitive information . . . aimed at driving up prices." *Id.* ¶ 21.

Defendants ignore the SAC allegations concerning how their rebate agreements with the drug manufacturers were anticompetitive and resulted in harm to both SilverScript beneficiaries and the Government. Instead, much of Defendants' argument is premised on a fundamental untruth: "the decision to cover and include a brand drug on a formulary," to the exclusion of competitor drugs, "is lawful" under all circumstances. *See* Br. at 11. That assertion is both legally and factually wrong. Defendants' interactions with drug manufacturers are subject to antitrust laws, which prohibit the anticompetitive conduct in which they have participated.

The allegations in the SAC, which must be accepted as true for the purposes of Defendants' motion, *see Anjelino*, 200 F.3d at 87, detail how Defendants' conduct was unlawful under the antitrust laws.[10] For each of the drugs at issue, Defendants participated in unlawful anticompetitive conduct that stifled generic competition and restricted patients' access to cheaper drugs. *See, e.g.*, SAC ¶¶ 6, 291, 370-78 (Copaxone), 399-406 (Invega), 424-35 (Asacol HD), 456-66 (Renvela), 495-503 (Harvoni/Epclusa), 616-27 (Ventolin HFA), 645-49 (Canasa), 679-85 (Advair Diskus). Pursuant to the rebate agreements between drug manufacturers and CVS Caremark, "SilverScript was required to block substitution on its formularies of generic drugs in favor of the much more expensive brand-name" drugs. SAC ¶ 9. These agreements "became key to facilitating the Drug

[10] *See, e.g.*, *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d Cir. 2012) ("The primary antitrust concern with exclusive dealing arrangements is that they may be used by a monopolist to strengthen its position, which may ultimately harm competition."); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 236 (1st Cir. 1983) ("The antitrust problem that courts have found lurking in requirements contracts grows out of their tendency to 'foreclose' other sellers from the market by 'tying up' potential purchases of the buyer. Arguably, under certain circumstances substantial foreclosure might discourage sellers from entering, or seeking to sell in, a market at all, thereby reducing the amount of competition that would otherwise be available.").

Makers' evergreening, pay-for-delay, product hopping, sham patent litigation, sham Citizen's Petitions, authorized generic and other schemes (used in combination or separately) to block generic competition." *Id.* ¶ 6. Thus, Defendants "aided and abetted the drug manufacturers competing not solely on the basis of innovation, but rather on their ability to obstruct access to generic competition." *Id.* Defendants' anticompetitive conduct caused, or caused to be submitted, false claims to the Government, which is actionable under the False Claims Act. *Id.* ¶¶ 8, 21, 55-59, 217, 289, 339, 348, 621.

Ellsworth does not argue, as Defendants contend (Br. at 9), that Medicare Part D sponsors may never "choose to cover the brand drug but not its generic equivalent." Indeed, there may be circumstances in which legitimate market forces would justify such a result and lead to lower prices for consumers. But the circumstances here are far different. Defendants kept costlier brand-name drugs on their formularies and excluded cheaper generic drugs not because of legitimate market forces or a commitment to patient well-being, but because of anticompetitive agreements with drug manufacturers that benefitted Defendants' bottom line. *See, e.g.*, SAC ¶¶ 370-98 (Copaxone product hopping and evergreening scheme), 399-421 (Invega authorized generic agreement), 422-55 (Asacol HD pay-for-delay, rebate wall, and authorized generic schemes), 465-82 (Renvela pay-for-delay and authorized generic scheme), 493-612 (Harvoni/Epclusa authorized generic scheme), 613-44 (Ventolin HFA evergreening and authorized generic scheme), 645-78 (Canasa pay-for-delay and authorized generic scheme), 679-711 (Advair Diskus evergreening and authorized generic scheme); *see also id.* ¶ 8 ("[W]ith all its wholly-owned subsidiaries conspiring together, CVS Health has been able to achieve an 'enterprise-wide benefit' from the anticompetitive deals with the Drug Makers that has padded its bottom line, but has harmed taxpayers as well as elderly, ESRD and disabled Part D beneficiaries.").

In exchange for rebates paid to Defendants by the drug manufacturers, Defendants agreed to assist drug manufacturers in blocking patients from securing cheaper generic medications, thereby depressing competition and keeping drug prices artificially high. *See* SAC ¶¶ 11, 313, 323, 524, 553, 584, 594, 638, 691 (identified beneficiaries whose access to generic drugs was blocked); *id.* ¶¶ 6-7, 137, 289, 368-71, 374, 621 (agreements foreclosed possibility of generic competition). But for these unlawful agreements, beneficiaries would have had access to generic equivalents because pharmacists in the seventeen mandatory-substitution jurisdictions would have been required to comply with the law, and pharmacists in the permissive-substitution jurisdictions would have been empowered to substitute lower-priced generics.

Defendants also engaged in deceptive conduct that defrauded beneficiaries and the Government. For example, Defendants discouraged beneficiaries from seeking formulary exceptions for generic drugs by misleading them into believing that generic drugs, because they were off-formulary, would be more expensive than the on-formulary brand-name drugs. SAC ¶¶ 384, 388, 440, 444, 508, 512, 518, 522, 635, 654, 658. Defendants misrepresented that generic drugs were unavailable due to circumstances outside Defendants' control, *id.* ¶¶ 385, 411, 441, 472, 481, 509, 519, 633, 655, 691, which was untrue, *id.* ¶¶ 386-87, 412-13, 442-43, 472-73, 482-83, 510-11, 520-521, 634, 656-57, 692-93. As to two brand-name drugs, Harvoni and Epclusa, Defendants represented that formulary exceptions for those drugs' generic equivalents were available, but then issued blanket denials for all such formulary exceptions. *Id.* ¶¶ 14, 280, 500, 505, 508, 512, 515, 522, 540-554, 559, 577, 600, 605, 608. And as to four brand-name drugs, Defendants required their CVS Pharmacies not to stock the generic versions of those drugs, eliminating any possibility that a beneficiary could ultimately obtain a cheaper generic over a brand-name drug. *Id*. ¶¶ 14, 278, 541, 557, 575, 598. As a result of this conduct, beneficiaries

and the Government paid higher prices for brand-name drugs than they otherwise would have. *See, e.g.*, *id.* ¶¶ 14, 64, 227, 243, 302, 366, 375, 566 (Beneficiary No. 8). Thus, Relator has more than adequately alleged that Defendants' anticompetitive conduct defrauded the Government within the meaning of the FCA.

Significantly, Defendants do not deny that they engaged in any of this anticompetitive behavior, nor do they even deny that this behavior violates federal antitrust laws. Rather, their only defense is to assert that "CMS nowhere obligates plans to cover generics nor withholds approval of formularies that include a brand but not its generic equivalent." Br. at 7. But this assertion confuses CMS's limited role in Part D oversight with Defendants' overarching obligations to comply with federal law. Congress's admonition that CMS may not "interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors," 42 U.S.C. § 1395w-111(i)(1), does not supplant the entire field of antitrust law. Nor are Ellsworth's FCA claims based on Defendants' mere choice to cover brand-name drugs, rather than generics, on its formularies. Rather, Relator's claim is based on Defendants' anticompetitive and deceptive conduct in administering its Medicare Part D plan that effectively blocked beneficiaries from access to lower-priced generic drugs, resulting in higher costs for both beneficiaries and the Government. Because Defendants have not disputed those allegations, Relator's claim should proceed.

B. Relator Has Adequately Alleged False Certification Claims.

In addition to its claim for anticompetitive conduct in violation of the FCA, Relator alleges a number of false-certification claims under the FCA. "[A] claim is legally false when the claimant knowingly falsely certifies that it has complied with" a material statute, regulation, or contractual provision. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). A false certification may be either express or implied. "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance

with regulations which are prerequisites to government payment in connection with the claim for payment of federal funds." *Id.* (quoting *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297, 303 (3d Cir. 2008)). Implied false certification liability "attaches when a claimant seeks and makes a claim for payment from the government without disclosing that it violated regulations that affected its eligibility for payment." *Id.*; *see also Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 186-87 (2016). Ellsworth makes allegations under both theories of legal falsity. The alleged false certifications fall into two categories: (1) express false certifications of accuracy in claims data submitted by the CVS Health entities, and (2) express and implied false certifications of compliance with federal laws and regulations governing Medicare Part D.

Specifically, the SAC alleges six ways in which Defendants submitted false claims or caused false claims to be submitted. Defendants (1) violated state generic-substitution laws, (2) submitted data to CMS with false DAW codes, (3) systematically and improperly denied formulary exception requests, (4) fraudulently marketed their Medicare Part D plan, (5) fraudulently certified that their compliance program satisfied federal law and (6) breached promises made to the FTC. As explained below, every time Defendants submitted, or caused to be submitted, claims for payment under Medicare Part D, they expressly or impliedly certified that they had complied with these requirements, when in fact they had not.

Defendants challenge the adequacy of these allegations on three grounds: falsity, materiality, and scienter. Defendants' arguments are meritless.

1. The SAC Adequately Alleges That Defendants Falsely Certified Their Compliance with State Mandatory Generic-Substitution Laws

Sixteen states, as well as Puerto Rico, require pharmacists to substitute a generic drug for its brand-name equivalent in most or all circumstances.[11] As Defendants acknowledge, the intent of generic substitution laws[12] is to reduce healthcare costs through the use of less-costly generic drugs.[13]

The SAC alleges that, in states with mandatory generic substitution laws, the pharmacy must dispense a generic drug if the generic drug is cheaper for the patient. SAC ¶¶ 182, 269, 636. Because Defendants systematically denied access to generic drugs, regardless of price, they failed to comply with these mandatory generic substitution laws. *Id.* ¶¶ 189, 192. Defendants nevertheless sought reimbursement from the Government for these invalid prescriptions. *Id.* ¶¶ 24, 324, 396, 571, 668. Thus, Defendants falsely certified that they were filling valid prescriptions and submitting correct PDE records, both of which are requirements for reimbursement. *Id.* ¶¶ 71-73, 168-69, 174-75, 207, 329, 336. Defendants' reimbursement requests, therefore, were false claims.

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[11] *See* Appendix: Generic Substitution Laws. These laws generally include exceptions for when generic substitution is not warranted, such as when the prescriber orders the medication to be dispensed as written, when the pharmacist determines that the generic drug is not therapeutically appropriate for the patient, or when the patient does not give consent to the substitution.

[12] Relator does not concede, as Defendants argue (Br. at 23), that the scheme "cannot possibly" have caused false claims outside of the mandatory-substitution states. Defendants' misconduct interfered with pharmacists not only in mandatory-substitution jurisdictions, but in the permissive-substitution jurisdictions as well. The state generic-substitution laws are well-recognized pro-competitive tools to reduce the cost of prescriptions. *See* SAC ¶ 204. By removing the ability of pharmacists to substitute lower-priced generic drugs even if they wanted to, Defendants unlawfully increased the amounts patients and the Government paid, in violation of the FCA.

[13] *See* SAC Ex. 8 (CVS-001794) ("[T]he intent of these stricter pharmacy substitution laws is that consumers of prescription drug products may realize cost savings by buying less expensive, safe drug products.").

As a preliminary matter, Defendants make two fundamental errors with respect to the content of these laws. *First*, Defendants falsely claim that under the laws of three states, "generic substitution is not required where the prescribed brand drug is on the plan's formulary . . . but the generic equivalent is not." Br. at 23. However, Minnesota and Nevada, two of the states identified by Defendants, require only that the generic equivalent be covered by the plan *or* that the generic equivalent would carry a lower cost for the consumer.[14] Both situations are applicable here: the generic equivalent can be a covered drug when covered via a formulary exception and the generic drug can be cheaper for the consumer even when paid for in cash. That is because non-formulary drugs that are approved under a formulary exception are deemed to be "covered" under Medicare Part D. *See* CMS, *Medicare Prescription Drug Benefit Manual: Chapter 6 – Part D Drugs and Formulary Requirements* (hereinafter "*PDB Manual*") § 10.2 (2016), *available at* www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf ("A covered Part D drug is a Part D drug that is . . . treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal . . . .");[15] *see also* 42 C.F.R. §§ 423.100 (definition of "Covered Part D Drug"), 423.566 (coverage determinations), 423.578(a), (b) (exceptions process). Defendants also invoke the law of Tennessee, which does not require mandatory substitution "[i]f a pharmacist has reason to believe

[14] Minnesota and Nevada do not require mandatory substitution if the substitution will make the transaction ineligible for third-party reimbursement. Minn. Stat. § 151.21(5); Nev. Rev. Stat. § 639.2583(7)(c)(2). Nevada further exempts transactions that "[w]ould violate the terms" of the plan. Nev. Rev. Stat. § 639.2583(7)(c)(1). Neither of these circumstances is implicated by the facts of this case, in which the patients in the SilverScript plans would have realized substantial savings if they were lawfully granted formulary exceptions in accordance with the plan terms.

[15] The Court may take judicial notice of this document because it is a "readily available guidance document[] whose accuracy" cannot be questioned. *See Travis*, 2022 WL 991382, at *7. Moreover, "information found on government websites is widely considered both self-authenticating and subject to judicial notice." *Sturgeon*, 438 F. Supp. 3d at 259.

that the brand-name drug or drug product is less expensive to the patient or patient's drug plan than the generic equivalent," Tenn. Code § 53-10-205(d)(1), but the extent to which Defendants' pharmacists held these beliefs is a fact question inappropriate for resolution at this stage of the litigation. *Second*, the measure of "cost" or "savings" under these statutes is far from "ambiguous." *See* Br. at 24. The laws of New Jersey and Wisconsin, for example, explicitly state that these terms apply to the patient's financial responsibility[16]—not the pharmacy's acquisition cost or the plan's cost—and the remainder of the statutes are likewise plainly intended to realize savings for the patient.[17]

Defendants halfheartedly contend that a pharmacist has no role in determining the particular drug to be dispensed pursuant to a prescription. Br. at 30 n.14. But pharmacies and pharmacists are not vending machines; they play an integral part in drug distribution and have "a corresponding responsibility for proper dispensing of" medications. *Cf. In re Nat'l Prescription Opiate Litig.*, No. 18-OP-45032, 2022 WL 671219, at *2 (N.D. Ohio Mar. 7, 2022); *Correa v.*

[16] N.J. Stat. § 24:6E-7 (must substitute drug that will result in "a lower cost to the consumer"); Wis. Stat. § 450.13(1s) (must substitute generic if "lower in price to the consumer" than brand-name drug).

[17] Defendants' contention that the "the enrollee would always be paying the full retail price for the off-formulary generic equivalent instead of incurring out-of-pocket costs that count toward her coverage" (Br. at 25) is flawed for two reasons. *First*, whether a patient would realize cost savings even under Defendants' contorted reading of the law is a fact question that cannot be resolved at this stage. *Second*, Defendants' argument misconstrues the allegations in the SAC. Because Defendants would have been obligated to grant any formulary exception requests and cover sixty percent of the cost of these generic drugs but for Defendants' unlawful anticompetitive behavior, there is no need to consider whether Defendants' enrollees would accumulate spending under their Medicare benefits.

Likewise, Defendants' assertion that pharmacists would need "to engage in a comprehensive pharmacoeconomic analysis" (Br. at 37) is similarly flawed, as Defendants again appeal to a factual dispute that cannot be resolved on a motion to dismiss. In addition, not only would it have been simple for CVS's pharmacists to compare a patient's costs for an expensive brand-name drug to a generic equivalent under Tier 4 coverage, but Defendants' vertical integration—controlling and colluding between the PBM, healthcare plan, and pharmacy—would make any such calculation a simple matter.

Schoeck, 98 N.E.3d 191, 199 (Mass. 2018) ("[P]harmacies have a duty to fill prescriptions correctly."). Notwithstanding Defendants' attempt to balkanize the prescription process, separating prescribers and pharmacists into entirely distinct roles, both "[p]rescribers *and pharmacies* remain subject to applicable State laws regarding valid prescriptions" for the purposes of Medicare. 77 Fed. Reg. at 22152 (emphasis added).

Defendants largely resort (Br. at 26-29) to challenging the SAC's factual assertions concerning the difference in price between the more expensive brand-name drugs that were prescribed and the less expensive generic drugs that ought to have been dispensed. However, this argument is inappropriate. To begin, it contradicts the allegations in the SAC. While Defendants claim that cost comparisons are nearly impossible and their denial of access to generic drugs may have resulted in cost savings,[18] the SAC provides numerous specific examples of actual SilverScript patient claims demonstrating that the generic would have been much cheaper than the brand-name drug. *See* SAC ¶¶ 394-396, 491, 561-563. Defendants' cherry-picked examples of drug pricing at a single pharmacy and at a single point in time (Br. at 28) are hardly relevant to the wide range of false claims asserted in the SAC, and also ignore that these drugs ought to have been covered on Tier 4 via a formulary exception. *See Victaulic Co. v. Tieman*, 499 F.3d 227, 237 (3d Cir. 2007) ("Taking a bare 'fact' that is reflected not in the pleadings, but on a corporate website, and then drawing inferences *against* the non-moving party so as to dismiss its well-pleaded claims . . . , takes us, as a matter of process, far too far afield from the adversarial context of litigation."). Moreover, the precise extent to which Defendants' unlawful scheme resulted in monetary harm to the Government and SilverScript beneficiaries is a fact question inappropriate for resolution at the

[18] The fact that Defendants went to great lengths to cover up their conduct belies their assertion that they believed their conduct resulted in cost savings.

pleading stage. Drug pricing is complicated and fact-dependent. Defendants' sweeping generalities based on unrepresentative examples do not disprove Relator's theory and should be rejected, particularly before any discovery has taken place.

i. Defendants' Falsehoods Were Material

Defendants claim that their misconduct was immaterial because "the relator has not alleged any facts showing that 'the Government consistently refuses to pay claims in the mine run of cases based on noncompliance' with state generic-substitution laws." Br. at 38 (quoting *Escobar*, 579 U.S. at 195). Defendants badly misread the applicable case law. The definition of "material"—which Defendants entirely omit from their brief—is "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). This standard does not require proof of but-for causation—*i.e.*, but for defendant's fraud, the Government would not have paid the claim. Relator need not establish that the Government's payment decision would have been different, only that Defendants' misconduct was "capable of influencing" that decision.

Defendants selectively quote from and distort the Supreme Court's holding in *Escobar*, which held that "proof of materiality *can include*, *but is not necessarily limited to*, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Escobar*, 579 U.S. at 194 (emphasis added). The Supreme Court also opined that "the Government's decision to expressly identify a provision as a condition of payment," as well as whether the Government "pays a particular claim" or type of claim "despite its actual knowledge that certain requirements were violated," are relevant to the materiality inquiry. *Id.* at 194-95. In addition, it is relevant "whether the noncompliance is 'minor or insubstantial' or, instead, goes 'to the very essence of the bargain.'" *United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union No.*

98 v. Farfield Co., 5 F.4th 315, 346 (3d Cir. 2021) (quoting *Escobar*, 579 U.S. at 194, 196 & n.5). However, these factors were never intended to be a comprehensive checklist of the only issues relevant to materiality; rather, they function as guideposts for the lower courts to use in assessing whether any particular misconduct is material. In sum, *Escobar* "makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive." *See, e.g.*, *United States. ex rel. Escobar v. Univ. Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) (on remand); *accord Farfield*, 5 F.4th at 342 ("A materiality inquiry under the FCA is a holistic, totality-of-the-circumstances examination . . . ."). Defendants' argument collapses all of the *Escobar* materiality factors into one, ignoring that (1) *Escobar* listed several factors relevant to materiality, (2) no single factor is determinative, and (3) the factors enumerated by the Supreme Court are not exhaustive. Based on the totality of the circumstances, Defendants' misconduct was material.

Defendants assert (Br. at 30) that "the relator has not identified any indication from CMS that non-compliance with a state generic-substitution law renders a claim for an undisputedly covered brand drug non-reimbursable." This is false. The SAC alleges that a Part D sponsor may pay—and CMS will reimburse—only for drugs dispensed upon a "valid prescription." 42 C.F.R. § 423.104. A "valid prescription" is defined according to state law. *Id.* § 423.100. The SAC further alleges that in the mandatory substitution states, state law requires generic substitution for the prescription to be valid. SAC ¶¶ 22, 182, 206, 208, 212, 269, 322-24, 328-30, 333-35.

Furthermore, Defendants' misconduct went to the heart of the bargain between Defendants and the Government because it affected the amount of money the Government reimbursed Defendants for prescriptions. By engaging in unlawful anticompetitive conduct and restricting patients' access to cheaper generic medications, Defendants caused the Government to reimburse

for more expensive brand-name medications and pay more than it should have. Extensive precedent supports the proposition that a false claim is material when it affects the price the Government pays for a product or the amount of money the defendant receives. *See United States ex rel. Prose v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732, 743 (7th Cir. 2021) ("The size of the price differential alone offers strong support for a finding of materiality: it is hard to see why the government would be indifferent about paying $3,180 for services that should have been at the $54 level."); *United States ex rel. Stepe v. RS Compounding LLC*, 325 F.R.D. 699, 706-07 (M.D. Fla. 2017) (allegations of inflated prices charged to TRICARE sufficient to demonstrate materiality). *Cf. United States ex rel. Garbe v. Kmart Corp.*, 824 F.3d 632, 639 (7th Cir. 2016) ("[T]o the extent Kmart made false claims, they were material: those claims were the basis of the federal monies Kmart received.").

ii. Defendants Acted Knowingly

Defendants contend that their misconduct was motivated by "reasonable interpretations of the federal rules and state laws," such that they could not have acted knowingly. Br. at 32. This argument is unavailing for three reasons. *First*, Defendants' reliance on the scienter analysis set forth in *Safeco* is misplaced. Defendants have failed to cite any binding precedent in this circuit applying that standard to the FCA, and a fair reading of *Safeco* demonstrates that it does not apply here. The construction of a term of scienter "is often dependent on the context in which it appears." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 57 (2007). In *Safeco*, the Supreme Court applied the common-law definition of "reckless disregard" to the Fair Credit Reporting Act ("FCRA") because there was "no indication that Congress had something different in mind." *Id.* at 69. However, the Supreme Court has cabined this ruling to the particular context of the FCRA and has declined to extend it to situations where a party's subjective bad faith is relevant. *See, e.g.*, *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 & note (2016) (distinguishing *Safeco* in a Patent Act case).

The FCA, with its carefully enumerated scienter standard that refers to a defendant's subjective state of mind, is such a situation. *See* 31 U.S.C. § 3729(b)(1)(A)(i)-(ii) ("knowing" includes "actual knowledge" and "deliberate indifference"); Br. for Amicus Curiae Sen. Charles E. Grassley in Support of Pet'rs at 4-8, *United States ex rel. Tracy Schutte v. SuperValu, Inc.*, No. 21-1326 (U.S. May 19, 2022) (collecting cases), *available at* https://www.supremecourt.gov/DocketPDF/21/21-1326/225832/20220519154806836_21-1326%20Amicus%20Brief.pdf. Unsurprisingly, then, the Third Circuit has held that "reckless disregard" requires an inquiry into a party's "subjective awareness," foreclosing the application of *Safeco*. *See United States v. Caminos*, 770 F.2d 361, 366 (3d Cir. 1985).

Second, even if the *Safeco* standard applied to this case, Defendants have failed to identify any ambiguity in the laws and regulations at issue such that their interpretation of the laws at issue could be objectively reasonable. A claim is not payable unless it is made for a "valid prescription," which is defined according to state law, and the mandatory-substitution jurisdictions require that a prescription for a brand-name drug be substituted with a generic drug. *See supra* pp. 12, 22-30. This conclusion is further bolstered by CMS's DAW Codes, which do not permit a pharmacist to report that he or she has filled a prescription with a brand-name drug in a mandatory jurisdiction state.

Third, "a matter involving state of mind . . . is unsuitable for resolution at the motion to dismiss stage." *Jackson v. Se. Pa. Transp. Auth.*, No. CIV.A.08-4572, 2009 WL 637460, at *7 (E.D. Pa. Mar. 10, 2009); *see Pryor v. Nat'l Collegiate Athletic Ass'n.*, 288 F.3d 548, 565 (3d Cir. 2002) ("[I]ssues involving state of mind . . . are often unsuitable for a Rule 12(b)(6) motion to dismiss."). Determining the extent to which Defendants were warned away from their interpretation requires a fact-intensive inquiry that is not susceptible to resolution at this stage. *See*

United States ex rel. Streck v. Bristol-Myers Squibb Co., 370 F. Supp. 3d 491, 497 (E.D. Pa. 2019) ("Whether the proposed rule warned BMS away presents a question of fact.").

2. Defendants Submitted False Claims by Using False DAW Codes

"CMS requires Plan Sponsors to submit data, referred to as PDEs, for each prescription for which the Plan Sponsor has paid. PDE data are used, in part, to validate claims, monitor quality, and make year-end risk corridor calculations." SAC ¶ 151 (footnote omitted). PDE data include various fields, including Field 18: "DAW/Product Selection Code." *Id.* ¶¶ 152-56. This code indicates whether a generic or brand-name drug was dispensed and why. *Id.* ¶¶ 156-59.

As explained above, *supra* p. 11, "if a pharmacy dispenses a brand-name when a generic was available, the DAW code needs to reflect an accepted reason why." SAC ¶ 186. DAW codes from 0 to 9 provide these reasons. By formulating the PDE system in this manner, CMS has indicated that these are the *only* situations in which a pharmacy may dispense a brand-name drug instead of an available generic in a mandatory-substitution state.

DAW code 0 can be used in only two situations: (A) where a brand-name drug was dispensed because there are no generic equivalents, or (B) where a generic drug was dispensed instead of a brand-name drug. CVS Caremark's own Administrative Manual agrees, admonishing pharmacies to use DAW code 0 only when dispensing a brand-name drug "because generic substitution is *impossible*." SAC ¶ 163. CVS's Provider Manual echoes this guidance: "DAW 0 cannot be submitted on a multisource drug with available generics." *Id.* ¶ 183.

Defendants' fraudulent scheme involved the systematic misreporting of claims data using knowingly inaccurate DAW codes, which were used to support Defendants' claims for reimbursement from the Government under Medicare Part D. These inaccurate DAW codes misrepresented the nature of the drugs Defendants dispensed and the reasons for doing so. The SAC includes numerous examples of Defendants dispensing brand-name multiple-source drugs

and reporting DAW code 0 in mandatory substitution states. SAC ¶¶ 335, 569, 669. DAW code 0 indicates that no generic exists or that the prescriber issued the generic drug, but neither was true here. The SAC also includes an example of Defendants reporting DAW code 9 in a mandatory substitution state.[19] SAC ¶ 337. But DAW code 9 applies only where substitution is *permitted* and the plan requests the brand. It does not apply where substitution is *required*. In addition, the SAC includes examples of DAW codes being used improperly even in permissive-substitution states—such as reporting DAW code 0 (no generic exists), 1 (physician requested brand), or 2 (patient requested brand) when, in reality, the plan refused to dispense the generic drug and should have reported DAW code 9. *E.g.*, *id.* ¶¶ 391, 488, 552, 591, 636, 669 (0 instead of 9), 397, 489 (1 instead of 9), 638 (2 instead of 9). All of these false statements provided misinformation about what drugs were being dispensed and why.

Defendants contend (Br. at 44) that this systematic fraud could not have been material "because the only drug that would be reimbursed by the plan is the brand, across the board." This contention is factually false. As alleged throughout the SAC, Defendants were required to cover non-formulary drugs through Tier 4 cost-sharing. SAC ¶¶ 280, 378, 386, 406, 435, 438, 442, 466, 503, 506, 510, 516, 520, 631, 647, 650, 654. Moreover, it misses the point. Whether the plan would have reimbursed for a prescription is a distinct question from whether the Government would reimburse for a prescription. CMS needs to know not only *what* it is reimbursing, but *why*

[19] The SAC further alleges that Defendants improperly used DAW code 5 (brand-name drug dispensed as generic) even though Defendants failed to give their enrollees and CMS the benefit of generic pricing. *Id.* ¶ 336. Although the SAC does not include any examples of this particular type of miscoding, it nonetheless provides numerous particularized examples of how Defendants' miscoding scheme worked generally. *See Foglia*, 754 F.3d at 156 (complaint must provide only "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted," not "the exact content of the false claims in question"). Accordingly, the Court should reject Defendants' request (Br. at 37) to dismiss the SAC on this ground.

it is making that payment. Inaccurate DAW codes prevent CMS from determining plan sponsors' compliance with the Medicare Part D rules.

Unsurprisingly, Defendants say little about *U.S. ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 38 F. Supp. 3d 398 (S.D.N.Y. 2014), where the court held that incorrect DAW codes in PDE records could be the basis for FCA violations. The relator in *Fox* alleged that the defendant pharmacies failed to substitute generic drugs for brand-name drugs in states mandating such substitution by law. *Id.* at 401. According to the court, if the pharmacies had submitted PDE records, they would have violated a condition of payment under Medicare. *Id.* at 411 (holding that 42 C.F.R. § 423.505(k)(3) "does relate directly to the payment of Part D claim . . . [and] requires a certification that the submitted [PDE] data is accurate, complete and truthful"). The *Fox* relator's allegations echo those of Relator, who has specifically alleged the violation of § 423.505(k)(3) due to false DAW codes. *See* SAC ¶¶ 171, 177.[20]

In addition, CMS guidance confirms that proper DAW codes are material to payment. CMS has identified the "inappropriate use of dispense as written ('DAW') codes" as an example of pharmacy fraud, waste, and abuse. SAC ¶ 174. CMS has also asked pharmacies to "[c]onsider the risk for fraud, waste, or abuse if pharmacy staff members adjudicate claims with inaccurate product selection [DAW] codes." *Id.* The SAC further alleges that DAW codes are "an integral part of accurate billing" and "[f]ailure to accurately use DAW codes results in misinformation to the Pharmacy program and its decision making process." *Id.* ¶ 173.

[20] The court's ultimate decision to dismiss the complaint was based on a misunderstanding—which the relator did not dispute—"that there is no federal regulation requiring substitution of a generic for a branded drug." *Fox*, 38 F. Supp. 3d at 412. As explained above, *see supra* pp. 12, 22-30, this is untrue.

The SAC also alleges that Defendants acted knowingly. Defendants argue (Br. at 36, 38) that Relator has not alleged a "broad scheme" to use incorrect DAW codes, claiming their misconduct was the result of "ordinary coding mistakes," and pinning the blame on an ostensibly neutral third party: "the pharmacist at the counter." These protestations ignore the allegations in the SAC. Ellsworth alleges that Defendants' fraudulent scheme to block generic competition in exchange for manufacturer rebates came from the highest levels of CVS Health and affected numerous companies under the CVS Health umbrella, including SilverScript, CVS Caremark, and CVS Pharmacies. SAC ¶¶ 18-19, 35, 213, 261, 269, 285, 496, 501, 525, 527, 622-23. Defendants attempt to draw arbitrary lines between its various entities, suggesting, for example, that "state pharmacy substitution laws are a pharmacy issue – and not a plan issue." *See* SAC ¶ 328 & Ex. 8 atCVS-001795. The SAC, however, alleges Defendants' top-down scheme removed any choice from pharmacies, such as forbidding CVS pharmacies from even stocking the generic versions of the drugs. *See, e.g.*, SAC ¶¶ 15, 246, 247, 280. And Relator has alleged that all the vertically integrated entities were aligned, thereby enabling Defendants' scheme. *Id.* ¶¶ 211, 217, 252, 261, 272, 275, 304, 325. Thus, construing the SAC's allegations in Relator's favor, any "mistakes" made in a CVS pharmacy's DAW coding were not "innocent," but rather purposeful efforts to cover up Defendants' scheme to avoid filling prescriptions with generic drugs, even when they were required to do so by state law. *Id.* ¶¶ 322-38. "The pharmacist at the counter" is anything but neutral—she works for Defendants. Defendants' systematic fraud, including "block[ing] substitution . . . of generic drugs in favor of the much more expensive brand-name" drugs, SAC ¶ 9, was a multi-pronged, coordinated effort among CVS's various subsidiaries. Read in context, Relator's DAW allegations provide a plausible inference that Defendants knowingly caused false claims to be submitted. *Foglia*, 754 F.3d at 156.

3. The SAC Plausibly Alleges that Denying Formulary Exceptions Caused False Claims to Be Submitted

Ellsworth details how CCRs systematically misled beneficiaries about the cost of non-formulary generics to create the impression they would be more expensive. SAC ¶¶ 384, 388, 440, 444, 508, 512, 518, 522, 635, 654, 658. The SAC explains that, even while it kept beneficiaries in the dark about other, cheaper options, between 2015 and 2018 SilverScript permitted beneficiaries to seek formulary exceptions as long as they were specifically requested and supported by the requisite information. *Id*. ¶ 316. This all changed when CVS Caremark entered into agreements in late 2018 with Gilead, whereby it agreed it would require SilverScript to deny all formulary exceptions for the cheaper (identical) generics of Harvoni and Epclusa. *Id*. ¶ 317.

The SAC explains that the CVS Caremark rebate agreement with Gilead required Defendants to deny all formulary exceptions for Harvoni and Epclusa without exception, SAC ¶¶ 14, 280, 541, 543-44, 559, 565, 577, 599-602, 605, telling beneficiaries that the brand-name and the generic "would be expected to have the same effectiveness in treating your condition. The brand drug on the formulary and its generic contain the same active medications. They both contain the same inactive ingredients such as dyes, and would be expected to have the same risk of causing adverse effects (side effects)." *Id*. ¶¶ 541-42. Not only is this "same effectiveness" language inherently misleading because all generic drugs, not just Harvoni and Epclusa, would fall into this category, but if the beneficiary cannot afford the brand-name drug, the brand-name cannot be as effective as the more affordable generic. *Id*. ¶ 542. The SAC identifies numerous specific beneficiaries whose access to the generic versions of Harvoni and Epclusa was blocked, *id.* ¶¶ 521-28 (Beneficiary No. 5), 529-37 (Beneficiary No. 6), 538-52 (Beneficiary No. 7), 553-72 (Beneficiary No. 8), 573-78 (Beneficiary No. 9), 579-83 (Beneficiary No. 10), 584-96 (Beneficiary No. 11), and hundreds of other SilverScript beneficiaries whose formulary exceptions

for these Gilead drugs were blocked, using this special blanket denial crafted just for Harvoni and Epclusa patients (*id.* ¶ 597).

Ellsworth also details how, beginning in late 2018, CVS Caremark's agreements with Gilead and GSK required that CVS Pharmacies would not stock the generic versions of the Gilead drugs (Harvoni and Epclusa) or the GSK drugs (Advair Diskus and Ventolin HFA). *Id.* ¶¶ 15, 244-45, 262, 278, 317, 350, 498, 528, 622-23. As a result, many of the 45 million Part D beneficiaries who fill their prescriptions at CVS Pharmacies, not just SilverScript beneficiaries, were unable to obtain the generics for Harvoni, Epclusa, Advair Diskus, and Ventolin HFA. *Id.* ¶¶ 278, 498, 622. Because Defendants were obligated to offer formulary exceptions for the generics of these drugs, Defendants' reimbursement claims to the Government for the more expensive brand-name drugs were false claims within the meaning of the FCA.

Defendants argue (Br. at 38-40) that Ellsworth has failed to state a claim because Defendants were not required to grant formulary exceptions unless the brand-name choice was clinically ineffective. This ignores the full text of the formulary exception rule, which *requires* a formulary exception if the formulary drug "would not be as effective for the enrollee as the non-formulary drug, *would have adverse effects for the enrollee*, or both . . . ." 42 C.F.R. § 423.578(b)(5)(i) (emphasis added). Defendants simply ignore the SAC's allegations that Defendants' formulary drugs (Harvoni and Epclusa) had "adverse effects" for beneficiaries because they were routinely significantly more expensive than the authorized generics. SAC ¶¶ 19, 523-612. Beneficiaries were adversely affected because, without a formulary exception, they and the Government were forced to make payments for Harvoni (costing $96,381 for a course of treatment) instead of its generic (costing $36,795 for a course of treatment), or for Epclusa (costing $75,552 for a course of treatment) instead of its generic (costing $24,249 for a course of treatment).

Id. ¶ 501. Because the brand-name formulary drugs were more expensive than the generics, beneficiaries suffered increased copayments that pushed them more quickly into the Catastrophic Stage of their Part D benefit, where beneficiaries and the Government pay greater out-of-pocket costs (*id.* ¶ 580). Many beneficiaries could not afford the more expensive brand-name drug. *See, e.g.*, *id.* ¶¶ 533-38 (Beneficiary No. 6); 588 (Beneficiary No. 11). Other beneficiaries were forced to delay needed treatment (*id.* ¶ 561 (Beneficiary No. 8)) or abandon their lifesaving medications altogether (*id.* ¶ 525 (Beneficiary No. 5); *id.* ¶ 596 (Beneficiary No. 11)). Those are plainly adverse effects that required Defendants to grant formulary exceptions.

The SAC further alleges that Defendants knew that denying formulary exceptions as a matter of course for the authorized generics of Harvoni and Epclusa would adversely impact SilverScript beneficiaries. CVS Health repeatedly recognized that the cost of drugs was a key factor for patients to be able to receive the medications that they need. *See, e.g., id.* ¶ 288 (CVS touted that it aimed to get the "right drug at the lowest possible cost for patients" because this allowed patients to "stay on the medications they need"); *id.* ¶ 296 (citing research that use of cheaper generics "improves outcomes and saves lives, largely because they are more affordable for patients and therefore increase patient adherence to their medicine"); *id.* ¶¶ 543-47 (stating that the affordability of care has a direct relation to clinical outcomes); *id.* ¶¶ 544-45.[21] Yet, the blanket denials for formulary exceptions for authorized generics of Harvoni and Epclusa blocked patients' ability to get access to more affordable drugs, which Defendants knew would adversely impact their ability to receive the drugs they need. *Id.* ¶¶ 14, 278, 541, 557, 575, 598.

[21] *See* SAC ¶ 545 n.344 (citing Josh Lee *et al.*, *Addressing the social determinants of health for Medicare and Medicaid enrollees* (2019), *available at* https://tinyurl.com/2p8ftdmw, and Tany Feke, *How Medicare Addresses Social Determinants of Health* (Oct. 25, 2020), https://www.verywellhealth.com/medicare-social-determinants-of-health-4587338).

Defendants' purported excuse for denying formulary exceptions for the authorized generics of Harvoni and Epclusa was plainly just that. *See* SAC ¶¶ 541-42. All generic drugs have the "same active medications" as the brand-name drug and "would be expected to have the same risk of causing adverse events," such that they should have the "same effectiveness." *Id.* Indeed, Defendants had never before invoked this "same effectiveness" excuse as a rationale to block access to other generics (*id.* ¶¶ 601-02), but limited this excuse to Harvoni and Epclusa, and only for their SilverScript business, for which the Executive Committee had concluded the limited risk of detection was offset by the CVS Health substantial financial gain (*id.* ¶¶ 19, 35, 114-18, 216, 266-67, 274, 498, 527, 529). *See also id.* ¶ 113 (Defendants did not apply the blanket denials of Harvoni and Epclusa to new enrollees because such conduct risked additional CMS auditor scrutiny). These allegations more than suffice at this stage of the pleadings to lead to "a strong inference that [false] claims were actually submitted." *Foglia*, 754 F.3d at 156.

Defendants contend (Br. at 39-40) that, even if they wrongfully denied formulary exceptions for authorized generics, their conduct was harmless because beneficiaries could have rectified such error by filing an appeal. Although beneficiaries may appeal denials of formulary exceptions, the SAC alleges that Defendants counted on the fact that the vast majority of beneficiaries, faced with intentionally deceptive statements that the generic alternatives would be more expensive, SAC ¶¶ 384, 388, 440, 444, 508, 512, 518, 522, 635, 654, 658, or were not available, *id.* ¶¶ 386-87, 412-13, 442-43, 472-73, 482-83, 510-11, 520-521, 634, 656-57, 692-93, would not appeal at all.[22] *Id.* ¶¶ 10, 19, 64, 106, 377, 439, 555. The result of Defendants'

[22] According to a study by the HHS Office of the Inspector General concerning Medicare Part D claims rejections, in 2017, only 0.3% of all claims resulted in beneficiaries making coverage determination requests to Part D Plan Sponsors. *See* U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs* (hereinafter "*OIG Report*") at 28 (2019), *available*

deception, therefore, was that beneficiaries who were denied formulary exceptions could not afford the drugs they needed or, at best, received them only after a delay. *Id.* ¶¶ 64, 302, 377. Such harm to beneficiaries was well known (and expected) by Defendants. *Id.* ¶¶ 15, 19, 35, 216, 263, 271, 287, 498, 503, 527, 529, 624, 627.

Indeed, the risk of such harm was forewarned in the September 2019 HHS Office of the Inspector General ("OIG") report concerning Part D coverage rejections, explaining that "these extra steps [in the administrative appeals process] may delay beneficiary access to needed drugs, or deter them from getting the drugs *if they are unable or unwilling to spend time navigating the approval process*." *OIG Report* at 11 (emphasis added). According to the OIG, a Part D Sponsor's complex coverage rules can "lead to confusion among prescribers and beneficiaries," and delay access to needed medications. *Id.* at 1. The OIG warned that "[w]hen beneficiaries do file formulary exception requests, the short timeframes required for processing requests (intended to promote timely access to needed drugs) often lead to denials if sponsors are not able to obtain supporting information within the allotted timeframe." *Id.* And "even low rates of denied or delayed medically necessary drugs or reimbursement *could contribute to physical or financial harm for many Medicare beneficiaries*." *Id.* (emphasis added).

This outright denial of a beneficiary's right to seek a formulary exception is exactly what happened to Beneficiary No. 15, a 78-year-old retired nurse from Massachusetts, who called in to CVS Health on February 29, 2019 to request a formulary exception to receive Wixela, the cheaper generic version of the brand-name drug Advair Diskus. As she had been instructed to do, the Customer Care Representative ("CCR") told Beneficiary No. 15 that she could not receive a

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at https://oig.hhs.gov/oei/reports/oei-09-16-00411.pdf. *See also Sturgeon v. Pharmerica Corp.*, 438 F. Supp. 3d at 259 ("information found on government websites is widely considered both self-authenticating and subject to judicial notice").

formulary exception for the generic drug: "[I]n cases where the note says dispense brand, you have to get the brand . . . . [T]here's no way you can get a formulary exception on that . . . ." SAC, Ex. 74 at 2. The CCR subsequently reiterated that "[t]here's no exception on that." *Id.* at 3. The allegations in the SAC (*i.e.*, that beneficiaries' access to cheaper generic drugs through a formulary exception was blocked) more than suffice to lead to an inference that Defendants' conduct caused false claims for the more expensive brand-name drugs to be submitted to the Government. *Foglia*, 754 F.3d at 156.

Defendants further argue (Br. at 39-40) that, absent allegations that the administrative review process "would have reversed the denial of these unwarranted formulary exceptions," Relator's claim, based on the denial of formulary exceptions, must fail. The Court, however, can take judicial notice of the OIG's findings that "Sponsors overturned 73 percent of drug coverage denials that were appealed" in 2017. *OIG Report* at 14. Not only that, but the OIG calculated that in 2017 (a) approximately 19% of the cases appealed to the next level, independent review entity, were overturned; (b) approximately 27% of the cases appealed to the next level, Office of Medicare Hearings and Appeals, were overturned; and (c) approximately 31% of the cases appealed to the next level, Departmental Appeals Board, were overturned. *Id*. at 29. Thus, the OIG Report suggests that a significant number of rejected claims are overturned on appeal such that, statistically speaking, a high percentage of Defendants' denials of formulary exceptions were likely improper and would have been reversed on appeal. But even putting that aside, "*[t]hese overturned denials could have been avoided if sponsors had received, and correctly processed, all relevant information at the first request*." *Id.* at PDF p. 2 (emphasis added). Thus, the SAC plausibly alleges that, for most SilverScript beneficiaries, the denial of a formulary exception harmed beneficiaries. Defendants knew that beneficiaries would be harmed because they would

either be discouraged from filing an appeal or would suffer substantial delay during the appeals process, even if such an appeal were ultimately successful.

4. The SAC Plausibly Alleges Defendants' Fraudulent Marketing Caused the Submission of False Claims.

The SAC alleges that SilverScript's solicitation materials provided to prospective Part D beneficiaries emphasize that it is "All about you," deceptively telling seniors that it will always act only on behalf of beneficiaries and not in its own self interest. *Id*. ¶ 234. Ellsworth alleges these marketing claims are materially inaccurate. *Id*. ¶ 241. For the fifteen identified brand-name drugs, SilverScript harmed beneficiaries by effectively preventing their access to less expensive generic versions of those drugs through denying and discouraging formulary exceptions. The SAC details that SilverScript's marketing materials fail to disclose that for many beneficiaries its brand-name formulary choices would actually drive their costs into the Donut Hole and Catastrophic Coverage Stages much sooner, dramatically increasing beneficiaries' out-of-pocket costs, as well as the Government's share of costs. *Id*. ¶ 242. Because of SilverScript's marketing misrepresentations and false promises, Part D beneficiaries were fraudulently induced to join SilverScript's plan, thereby causing beneficiaries to then submit false claims for the brand-name drugs to the Government. As a result, all claims for reimbursement which Defendants submitted, or caused to be submitted, to the Government were false claims. *See, e.g*., *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 500-01 (8th Cir. 2016) (false promise can be the basis for fraudulent inducement claim); *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173-74 (9th Cir. 2006) (same).

Defendants make four arguments (Br. at 40-44) that the SAC's marketing allegations are insufficient to state a claim under the FCA. All are incorrect.

First, Defendants claim (Br. at 41) that the SAC fails to allege a causal link between the fraudulent representations made and the submission of false claims. This circuit uses the "substantial factor" test to determine causation, asking whether the harm was a "normal consequence" of the situation created by the defendant's scheme. *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004); *see also United States ex rel. Galmines v. Novartis Pharms. Corp.*, No. CIV.A. 06-3213, 2013 WL 2649704, at *11 (E.D. Pa. June 13, 2013) ("[T]he complaint plausibly suggests that doctors wrote off label-Elidel prescriptions because of Novartis's marketing, and that Novartis's actions thus played a substantial and foreseeable role in the submission of false claims."), *modified in part on other grounds*, 2013 WL 5924962 (E.D. Pa. Nov. 5, 2013). That standard is easily satisfied here.

The SAC alleges that SilverScript's marketing materials falsely told seniors that they can "trust" SilverScript to act on their behalf "every day, in every way." SAC ¶¶ 236, 238-39. SilverScript's "Brand Promise" was that "every prescription is more than a mere transaction; each is a *commitment* to demonstrate our expertise and *sole focus* on delivering Part D coverage that helps participants on their path to better health." *Id.* ¶ 239 (emphasis added). Not only that, but SilverScript promised it would help beneficiaries "save money" and "cover the cost" of their expensive drugs. *Id.* ¶ 242. The glossy marketing promised seniors SilverScript would "protect your health savings." *Id.* ¶ 243.

These representations were materially misleading. One former SilverScript actuary admitted that SilverScript's marketing claims were often inaccurate, acknowledging that "there are winners and losers" as a result of Defendants' scheme. *Id.* ¶ 317. When he complained about the high cost of Copaxone for Part D beneficiaries, he was told the increased costs "were not an issue" because most of the costs for LIS beneficiaries would be subsidized by the Government,

underscoring that CVS Health management had little concern for the impact on non-LIS beneficiaries and the Government, who were the "losers" in the scheme. *Id.* ¶ 367. Not only that, but CVS Health knew that, even for many low-income LIS beneficiaries, the additional copayment cost (though minimal) for a brand-name drug would push them even further into poverty. *Id.* ¶¶ 14, 278, 541, 557, 575, 598. For example, when an 82-year-old Florida woman called to get a formulary exception for the cheaper generic form of Asacol HD, the message was "tough luck." *Id.* ¶¶ 241, 443-50.

Relator has thus more than adequately alleged that the fraudulent marketing materials were a substantial factor in causing SilverScript beneficiaries to choose its plans, relying on false promises that it would always act on their behalves, when in fact beneficiaries and the Government were generally on the losing end of Defendants' efforts to obstruct access to less costly generic drugs. These allegations offer a strong inference that beneficiaries relied on these fraudulent marketing representations in choosing a SilverScript plan, believing SilverScript would make less costly generic drugs available, only to learn later that their choices were limited to more expensive brand-name drugs, for which they submitted reimbursement claims to the Government. SAC ¶¶ 233-44. While these allegations alone offer a "strong inference" that false claims were submitted, the SAC provides numerous specific examples of false claims that were submitted to plausibly infer the fraudulent marketing caused the submission of false claims. *See also Purcell v. Gilead Scis., Inc.*, 439 F. Supp. 3d 388, 397-98 (E.D. Pa. 2020). Accepting as true all of Ellsworth's allegations, the SAC sufficiently alleges a normal consequence of the deceptive claims in the SilverScript marketing materials would be the submission of false claims to the Government.

Second, Defendants contend (Br. at 41-44) they have no liability with regard to their marketing materials.[23] This argument is unavailing. First, although they suggest that CMS approved their marketing materials (Br. at 41), even Defendants admit that CMS reviewed those materials only to ensure that they accurately reflected what was in their Part D bid. CMS's review would not have disclosed Defendants' systematic deception of beneficiaries or its blanket denials of formulary exceptions. CMS' approval, therefore, is by no means a get-out-of-jail-free card for Defendants at this stage of the pleadings.

Defendants' assertion (Br. at 42) that they had no obligation to warn beneficiaries that requests for formulary exceptions for cheaper generics would be blocked is simply not true. CMS regulations require SilverScript to provide "clear" and "accurate" (42 C.F.R. § 423.128(a)(2)) cost-sharing information such as copayments, deductibles, and coinsurance (42 C.F.R. § 423.128(b)(2)(iii)). CMS prohibits the distribution of "communications that are materially inaccurate, misleading, or otherwise make misrepresentations or could confuse beneficiaries." CMS, *Medicare Marketing Guidelines* § 30.7 (2018), *available at* https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf.[24] CMS also requires inclusion of disclaimers when benefit information is included in marketing materials. *Id.* at 63. No disclaimer warned prospective SilverScript enrollees that requests for formulary exceptions for certain generic drugs would be summarily denied, or that SilverScript would discourage beneficiaries from seeking

[23] The regulations Defendants cite were not effective until March 22, 2021, twenty months after the Ellsworth case was filed. *See Contract Year 2022 Policy and Technical Changes to the Medicare Program*, 86 Fed. Reg. 5864, 5864 (Jan. 19, 2021).

[24] The Court may take judicial notice of this document because it is a "readily available guidance document[] whose accuracy" cannot be questioned. *See Travis*, 2022 WL 991382, at *7. Moreover, "information found on government websites is widely considered both self-authenticating and subject to judicial notice." *Sturgeon*, 438 F. Supp. 3d at 259.

formulary exceptions by misleading them to believe that, even if they requested and obtained a formulary exception for a generic drug, the generic drug would be more expensive. SAC ¶¶ 243-48. Instead, when discussing benefit information, the SilverScript 2019 and 2020 Plan Decision Guides for prospective enrollees tout throughout only "low copays and coinsurance" and "[c]omprehensive coverage with low copays,"[25] *id.* ¶¶ 236, 238, with no warning whatsoever that they would have no access to less costly generics, even through requests for formulary exceptions.

Defendants' argument (Br. at 43) that 42 C.F.R. § 423.132 does not require Part D sponsors to inform beneficiaries of price differentials between brand-name drugs and generics relies on the palpably false premise that the regulation's reference to "covered drugs" means only formulary drugs. Not true. Non-formulary drugs that are approved under a formulary exception are "covered" under Medicare Part D. *See PDB Manual* § 10.2 ("A covered Part D drug is a Part D drug that is . . . treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal . . . ."). *See also* 42 C.F.R. §§ 423.100 (definition of "Covered Part D Drug"), 423.566 (coverage determinations); 423.578(a), (b) (exceptions process).[26] Nor does the rule require the beneficiary to ask for the generic via a formulary exception before the obligation

[25] The only disclaimers provided are about potential savings for using preferred pharmacies (p. 17, n. 5) and that the formulary may change at any time. Footnote 5 of the SilverScript 2019 Plan Decision Guide only notified beneficiaries that there would be a difference in savings if they used a "preferred" pharmacy: "Percent savings based on SilverScript preferred vs. standard pharmacy copays. Savings may vary by state, drug tier and coverage stage. Call Customer Care for specific pricing of your medications." Under "Benefit Reminders," the Guide provided language required by CMS in all marketing materials, stating only that "[t]he formulary and pharmacy network may change at any time. You will receive notice when necessary." Nothing in these disclaimers put prospective enrollees on notice of the SSG/DNS scheme to block access to cheaper generics.

[26] *See also Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4194, 4224 (Jan. 28, 2005) ("We use the term 'covered Part D drug' to refer to a drug that not only is a Part D drug, but that is included in a Part D plan's formulary or treated (through a coverage determination or appeal described in subpart M of this preamble) as being included in a Part D plan's formulary, and is obtained at a network pharmacy or at an out-of-network pharmacy in accordance with § 423.124 of our final rule.").

to disclose differential pricing arises. SAC ¶ 144.[27] This only makes sense. As CMS explained, "such disclosure will provide enrollees – many of whom may not know that less expensive generic equivalents are available – with valuable information that will save money for beneficiaries, Part D plans, and Medicare." SAC ¶ 148 (quoting 70 Fed. Reg. at 4276).

Defendants contend (Br. at 43) that the Call Center statements to beneficiaries were not misleading. But this argument simply ignores the SAC's well-pled allegations, including:

- When beneficiaries called to request access to cheaper non-formulary generic drugs, Defendants' CCRs were instructed to inform beneficiaries that they could request a formulary exception, but such an exception would be approved at the "highest cost share level." SAC ¶¶ 380, 388, 410, 437, 440, 444, 468, 471, 475, 477, 480, 484, 505, 508, 512, 515, 518, 522, 629, 632, 635, 651, 654, 658, 687, 690, 694. This language was intentionally deceptive because "highest cost share level" suggested that the generic drug would be more expensive than the brand-name, on-formulary drug, even

[27] Industry comments to the proposed regulations asked that pharmacies not be required to disclose pricing information unless the beneficiary had requested this information. CMS rejected this suggestion, responding that pharmacies must in all instances disclose the price of equivalent generic drugs:

> *Comment*: One commenter concerned with the burden on pharmacies to disclose pricing information stated that the disclosure requirement should be limited to cases in which an enrollee asks for this information at the pharmacy.
>
> *Response*: . . . **Part D plans must require network pharmacies**, except for those which we have specifically exempted from the requirement, **to disclose information about price differentials. We cannot limit this requirement to circumstances in which an enrollee specifically asks for the information.** Furthermore, **we believe such disclosure will provide enrollees**—many of whom may not know that less expensive generic equivalents are available—**with valuable information that will save money for beneficiaries, Part D plans, and Medicare**.

70 Fed. Reg. at 4275 (emphasis added).

though the generic drug approved through a formulary exception would have still been cheaper than the brand-name formulary drug. *See id.* ¶¶ 384, 388, 440, 444, 508, 512, 518, 522, 635, 654, 658.

- CCRs were to tell beneficiaries that generic drugs were not available on the formulary because of "market conditions outside [CVS Health's] control." *See id.* ¶¶ 385, 411, 441, 472, 481, 509, 519, 633, 655, 691. This was misleading, *see id.* ¶¶ 386-87, 412-13, 442-43, 472-73, 482-83, 510-11, 520-521, 634, 656-57, 692-93, because the non-availability of generics was a direct result of Defendants' formulary choices and their decision to discourage or block formulary exceptions.
- In calls and letters regarding two of the brand-name drugs at issue (Harvoni, Epclusa), Defendants misrepresented that beneficiaries could request formulary exceptions, even though Defendants, pursuant to their agreement with Gilead, had agreed to uniformly deny all such exceptions. *Id.* ¶¶ 14, 280, 500, 505, 508, 512, 515, 522, 540-554, 559, 577, 600, 605, 608.

Third, Defendants brazenly declare (Br. at 43-44) that, even if Defendants misled beneficiaries about the availability or pricing of non-formulary generics, they cannot be held liable because their obligation to disclose accurate information extends only to formulary drugs. As explained above, however, Defendants were required to share truthful information, including information about access to formulary exceptions for a "Covered Part D Drug." *See supra* pp. 45-46.

Fourth, Defendants argue (Br. at 44) that their interpretation of whether CMS required them to disclose truthful information about cheaper generic drugs, even if mistaken, was still "objectively reasonable" because the plan "chose not to cover" cheaper generic drugs. This

argument ignores the SAC's allegations that Defendants deceived beneficiaries into believing generic drugs covered under a formulary exception would be more expensive than on-formulary brand-name drugs. Thus, Defendants did not merely "cho[o]se not to cover" cheaper generics; they prevented beneficiaries from even determining whether those drugs could have been covered on the non-formulary tier, and at what price, in the first place. Since the statute went into effect on January 1, 2006 (42 U.S.C. § 1395w-101(a)(2)), Defendants have known that they could not make misleading statements about covered drugs, which includes drugs that could be covered pursuant to a formulary exception. Thus, Defendants knew that their deception of Part D beneficiaries meant it was defrauding the Government. SAC ¶¶ 1, 10, 24, 89, 276, 351, 475, 528-29, 625.

Moreover, Defendants' intentional concealment of their misconduct belies any argument that their view of the law was objectively reasonable. Defendants made considerable efforts to conceal their scheme to deceive vulnerable elderly, ESRD, and disabled beneficiaries. Publicly, when their senior officials were pressed whether they engaged in this kind of fraudulent conduct, they concealed their misconduct (SAC ¶¶ 23, 26, 113, 269-270, 288-290, 292-302, 305, 309-15, 320, 341, 546, 548, 659), instead telling policymakers that CVS Health was "committed to finding the right drug at the lowest possible cost for patients to ensure they are able to access and stay on the medications they need," SAC ¶ 288, and were focused on "developing strategies that help lower costs for clients and their plan members," *id.* ¶ 289. Defendants also sought to prevent CMS auditors from detecting their scheme, *id.* ¶¶ 113-18, 498, 529, 544, 626, including directing Ms. Miller to engage in an off-the-books tracking of whether Defendants' scheme would create enough "member disruption" to trigger CMS scrutiny. *Id.* ¶¶ 115-18. In addition, Defendants did not apply their scheme to new enrollees where it would be subject to additional CMS auditor scrutiny

(*id.* ¶ 113), but specifically limited their scheme to SilverScript Part D beneficiaries so that there would be less likelihood of customer pushback (*id.* ¶¶ 266-67). Such allegations of concealment strongly support an inference that Defendants knew their conduct was unlawful. *See, e.g.*, *United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 735 (N.D. Ill. 2020) (allegations of concealment "now push across the line and permit an inference that AbbVie knew its conduct was not permissible").

Accepting the factual allegations as true, and "making all reasonable inferences to be drawn therefrom in the light most favorable to the plaintiff," *Anthony v. Council,* 316 F.3d 412, 416 (3d Cir. 2003), the SAC plausibly alleges that the marketing materials were materially inaccurate and misleading in that they failed to disclose that Defendants were blocking beneficiaries' access to cheaper generic drugs by denying and/or discouraging formulary exceptions, thereby resulting in the submission of false claims for brand-name drugs.

5. The SAC Plausibly Alleges Defendants Falsely Certified Compliance with Federal Laws and Regulations

The SAC alleges an express false certification claim that Defendants falsely certified that their compliance program was adequate to ensure the integrity of its claims, falsely attested to the accuracy and truthfulness of the PDE claims submitted, and falsely certified that they complied with Federal laws and regulations "designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to . . . the False Claims Act . . . ." SAC ¶¶ 22, 69-73, 77-98, 212-19. These express certification claims are "well founded" in the law. *See United States ex rel. Wood v. Allergan, Inc*., 246 F. Supp. 3d 772, 813 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018). "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to

government payment in connection with the claim for payment of federal funds." *Wilkins*, 659 F.3d at 305.

Defendants contend (Br. at 44) that the SAC's allegations concerning its compliance program are inadequate and should be dismissed. Again, Defendants completely mischaracterize Relator's allegations. The SAC alleges that Defendants falsely certified compliance with the law when, in fact, they were systematically engaged in illegal conduct, deceiving Part D beneficiaries, and routinely blocking formulary exceptions for access to cheaper generic drugs. SAC ¶¶ 99-107, 219. Defendants falsely certified compliance with the law in order to evade detection. *Id.* ¶¶ 176, 329. SilverScript and its subcontractors certified they were in full compliance with Federal laws and regulations "designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to . . . the False Claims Act . . . ." *Id.* ¶¶ 73, 171, 177-78, 210. But that compliance program was a sham. *Id.* ¶¶ 214. As one example, wary that CMS would sanction CVS for non-compliance (as it did in 2012 and 2015, *id.* ¶¶ 108-13), CVS management directed Ms. Miller to monitor behind the scenes any "member disruption" regarding Defendants' scheme to block access to the generic versions of Harvoni and Epclusa to ensure that CMS would not become aware of the scheme and sanction it further (*id.* ¶¶ 113-16). When Ms. Miller raised a concern that this was a compliance violation, she was told that Defendants' senior managers, including Patrick Jeswald, Chief Compliance Officer, Medicare Part D, had already signed off. *Id.* ¶¶ 117-19.

The SAC thus more than adequately alleges that Defendants certified their compliance with regulations governing their receipt of federal funds even though Defendants knew that their conduct was not in compliance. *See, e.g.*, *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 158 (E.D. Pa. 2012) (Relator adequately alleged false certification claim with regard to Part D).

6. The SAC Plausibly Alleges False Claims for Violations of the Firewall and FTC Consent Order

The SAC further alleges that Defendants breached the terms of two agreements with the FTC—a firewall and a consent order—resulting in reverse false claims. Pursuant to the firewall agreement, CVS and Caremark vowed to maintain "stringent firewall protections between [its] CVS Pharmacy retail business and [its] CVS Caremark PBM business to prevent any anti-competitive activity." SAC ¶ 248. CVS Health represented that the "firewall policy prevents SilverScript employees from accessing competitively sensitive information Caremark has collected from health plans that compete with SilverScript in the Medicare Part D area. There are robust compliance protocols in place at CVS Health to prevent any improper exchanges of information across its business units." *Id.*

Following an FTC investigation into the potential anti-competitive effects of the CVS-Caremark merged retail pharmacy/PBM into one business, the FTC entered into a settlement and consent order with CVS, pursuant to which CVS admitted liability and agreed to pay $5 million to resolve allegations that it had lied about the pricing of drugs to induce beneficiaries to select Medicare Part D coverage from its subsidiary RxAmerica. *Id.* ¶ 257. In the Agreement and Consent Order, CVS agreed for a period of twenty years that it would not "misrepresent, in any manner, or assist others in misrepresenting, in any manner, directly or indirectly, expressly or by implication, the prices or costs associated with Medicare Part D prescription drug plans." *Id.* ¶ 259.

Defendants assert (Br. at 45-46) that Relator's reverse false claims, based on breaches of the FTC firewall and Consent Order, should be dismissed. They are mistaken.

First, Defendants argue (Br. at 45) that, because the 2007 FTC firewall[28] and 2012 FTC Consent Order are not themselves federal laws designed to prevent fraud, waste, and abuse, they cannot be the basis for a false certification claim. This misses the point entirely. Both the firewall and the Consent Order were *premised on* Federal Trade Commission ("FTC") laws regulating fraud against consumers. Indeed,

> Section 5(a) of the FTC Act provides that '**unfair or deceptive acts or practices** in or affecting commerce . . . are . . . declared unlawful.' 15 U.S.C. Sec. 45(a)(1). 'Deceptive' practices are defined in the Commission's October 14, 1983 Policy Statement on Deception as involving a material representation, omission or practice that is likely to mislead a consumer acting reasonably in the circumstances. An act or practice is 'unfair' if it 'causes or is likely to cause **substantial injury** to consumers which is **not reasonably avoidable** by consumers themselves and **not outweighed by countervailing benefits** to consumers or to competition.' 15 U.S.C. Sec. 45(n).[29]

As such, the laws underlying the firewall and the Consent Order are clearly intended to prevent fraud, waste, and abuse. Defendants' certifications that they were complying with FTC laws underlying the firewall and the Consent Order are exactly the kind of express false certifications that trigger liability under the FCA.

Second, Defendants assert (Br. at 45-46) that compliance with the firewall and Consent Order is immaterial because it has nothing to do with CMS's payment decision. Again, this misses the point entirely. Instead, Defendants are liable for violation of the firewall and the Consent Order

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[28] Defendants' footnote that "no firewall has ever existed" (Br. at 45, n.17) is belied by both the allegations in the SAC and the testimony of Melissa A. Schulman, CVS Health Senior Vice President, Government Relations, on behalf of the company before the New York State Assembly that the firewall had been part of its promise to the FTC in 2007 at the time of the merger between CVS and Caremark, as well as part of its Code of Conduct. SAC ¶ 252. She also confirmed that the firewall prevented the CVS Health entities from "coming together to maximize [its] power and profit." *Id.* ¶ 253.

[29] *See* FTC, *A Brief Overview of the Federal Trade Commission's Investigative, Law Enforcement, and Rulemaking Authority* (May 2021), https://www.ftc.gov/about-ftc/mission/enforcement-authority (emphasis in original).

under 31 U.S.C. § 3729(a)(1)(G), the "reverse false claims" provision, for "knowingly mak[ing], us[ing], or caus[ing] to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government." For example, by its terms, the 2012 Consent Order stated that, for a period of twenty years, CVS and its subsidiaries "shall not misrepresent, or assist others in misrepresenting, in any manner, expressly or by implication, the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans." SAC ¶ 259. The Commission explained that, "to the extent that [CVS Health] and/or any of its subsidiaries . . . violates the terms of the Commission's final order, such as by mispresenting the price or cost of Medicare Part D prescription drugs, it would be liable for civil monetary penalties of up to $16,000 per violation pursuant to Section 5(1) of the FTC Act." *Id.* ¶ 262. Pursuant to that provision, the SAC adequately alleges that, because Defendants violated the Consent Order, Defendants have "an obligation to pay or transmit money" to the Government, which they have concealed or avoided through the use of false records or statements.

Nor must Ellsworth allege that "CMS consistently refuses to make payments when there has been a violation" of the firewall or the Consent Order. *See* Br. at 46. Under the reverse false claims provision, Relator need only allege knowing retention of an overpayment. Whether CMS refuses to make payments in such circumstances is irrelevant. *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 255 (3d Cir. 2016) (CFI need only prove that Victaulic knew its pipe fittings were improperly marked and did not notify the Bureau of Customs and Border Protection); *United States ex rel. Prather. v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 774 (6th Cir. 2016) (Under § 3729(b)(3), "there is no . . . need to show the affirmative use of a false record or statement in connection to the avoidance of an obligation

to pay money to the United States . . . . [T]he knowing retention of an overpayment is enough." (citation and internal quotation marks omitted)); *see also* Joel Hesch, *Understanding the Revised Reverse False Claims Provision of the False Claims Act and Why No Proof of a False Claim is Required*, 53 UIC J. Marshall L. Rev. 461, 471 (2021).

The SAC alleges that Defendants knowingly violated the terms of the firewall (SAC ¶¶ 7, 9, 21, 95, 219, 250-54, 272-77, 327, 329, 343, 353, 626) and the Consent Order (*id.* ¶¶ 17, 21, 219, 247, 255-63, 274, 341, 343, 353, 530, 539, 574, 603, 609, 644, 711) through their scheme to deceive SilverScript beneficiaries and "once again [misled] beneficiaries 'expressly or by implication' about the prices or costs (in addition to access) of the SilverScript plan." *Id.* ¶ 261. Because Defendants knowingly refused to pay the fines owing under the firewall and the Consent Order, Relator has stated a claim that Defendants violated their obligations to pay the Government, which is an "established duty" as contemplated by 31 U.S.C. § 3729(b)(3). *See United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 4461793, at *1, *6-7 (E.D. Pa. July 21, 2015) (holding that the violation of a corporate integrity agreement created an "obligation," even though the agreement specified that "failure to comply . . . *may lead to* the imposition of" fines) (emphasis added)).

C. The SAC Adequately Alleges Conspiracy Claims

Defendants' argument (Br. at 46-48) that the SAC fails to state a conspiracy claim is deeply flawed, ignoring Ellsworth's well-pled allegations.[30] 31 U.S.C. § 3729(a)(1)(C) extends FCA liability to those who conspire to commit a violation of any substantive provision of § 3729(a). Contrary to Defendants' argument (Br. at 47-48) that the conspirators must have specifically

[30] Because Ellsworth only alleges a conspiracy count with regard to the CVS Caremark agreements with the drug manufacturers (Count III, SAC § 720-722), the Court need not address Defendants' intracorporate conspiracy argument as it is completely irrelevant.

agreed to violate the FCA, Section 3729(a)(1)(C) does not require explicit intent to violate the FCA itself. Rather, Section 3729(a)(1)(C) only requires a violation of the other provisions of Section 3729(a), including, for example, knowingly presenting, or causing to be presented, a false or fraudulent claim (§ 3729(a)(1)(A)) or knowingly making or causing to be made false records or statements material to a false or fraudulent claim (§ 3729(a)(1)(B)). To state a claim for conspiracy, Relator need only describe the general composition of the conspiracy, some or all of its broad objectives, and the general roles in the conspiracy. *See Rose v. Bartle*, 871 F.2d 331, 366-67 (3d Cir. 1989); *United States ex rel. Budike v. Peco Energy*, No. 07-4147, 2013 WL 5890650, at *5 (E.D. Pa. Nov. 4, 2013) (collecting cases). "The essence of a conspiracy under the Act is an agreement between two or more persons to commit a fraud." *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927, 2010 WL 5466043, at *9 (D.N.J. Dec. 30, 2010) (internal quotation marks omitted).

Defendants are mistaken that the SAC fails to allege how they conspired with the drug manufacturers and thereby caused the Part D program to be defrauded. Br. at 47-48. The SAC alleges how CVS Caremark and the drug manufacturers entered into rebate agreements whereby cheaper (often identical) generics would be blocked on SilverScript formularies (SAC ¶¶ 3-12), requiring SilverScript to deceive Part D beneficiaries about getting formulary exceptions to access these cheaper drugs (*id.* ¶¶ 354-711). Ellsworth alleges, for example, how CVS Caremark entered into the Copaxone "House Brand" scheme to block access to the cheaper generic (*id.* ¶¶ 372-78), quoting a Teva employee: "[I]f a doctor orders generic glatiramer or the pharmacy benefit [manager] mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all." *Id.* ¶ 376. But the Copaxone scheme between CVS Caremark and Teva meant that "many SilverScript beneficiaries were left holding the bag on increased costs for Copaxone in

the Catastrophic Coverage stage of their Part D benefit." *Id.* ¶ 377. Many beneficiaries could not afford the additional cost and were forced to skip their treatments. *Id*. The SAC further details the CVS Caremark deal regarding Harvoni/Epclusa with Gilead, requiring that SilverScript deny all formulary exceptions for the cheaper generic (*id.* ¶¶ 14, 114, 280, 294, 319, 495-503), and even requiring that CVS Pharmacies no longer stock the generic drugs (*id.* ¶¶ 15, 246-47, 264, 280, 319, 352, 500, 530). The SAC also details how the Defendants' agreement with GSK required the CVS Pharmacies not to stock the generic versions of either Ventolin HFA or Advair Diskus. *Id.* ¶¶ 15, 280, 319, 624-25. The SAC explains how the rebate agreements required Defendants to deceive Part D beneficiaries about the price and availability of generic drugs and facilitated the drug manufacturers' efforts to delay competition through evergreening, product hopping, pay-for-delay, sham patent litigation, sham Citizen's petitions, authorized generics, and other schemes (*id.* ¶¶ 6, 291, 370-78 (Copaxone), 399-406 (Invega), 424-35 (Asacol HD), 456-466 (Renvela), 495-503 (Harvoni/Epclusa), 616-627 (Ventolin HFA), 645-649 (Canasa), 679-685 (Advair Diskus).

Ellsworth thus more than plausibly alleges that these actions in furtherance of the alleged conspiracy were undertaken pursuant to rebate agreements between CVS Caremark and the drug manufacturers and that it was foreseeable that Defendants' conduct to block access to generic drugs would result in false claims being submitted to the Government. There is therefore little ambiguity in the SAC's allegations that Defendants agreed to enter into a conspiracy with the drug manufacturers and took actions in furtherance of that conspiracy. At the pleadings stage, these allegations provide sufficient circumstantial evidence from which the Court can easily infer the existence of an agreement to violate the FCA. *See Travis*, 2022 WL 991382, at *10 (E.D. Pa. Apr. 1, 2022) (Court can "infer the existence of an agreement" between Gilead and the PAN Foundation to violate the False Claims Act "by specifically directing donations to subsidize the copays of

patients who have been prescribed Sovaldi or Harvoni"); *United States ex rel. Boise v. Cephalon, Inc.*, Civ. No. 08-287, 2015 WL 1724572, at *14 (E.D. Pa. Apr. 15, 2015) ("[T]here is . . . little ambiguity in the second amended complaint's allegations that Takeda agreed to enter into a conspiracy with Cephalon and allegedly took actions in furtherance of that conspiracy."); *United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 523 (E.D. Pa. 2015) (finding "sufficient circumstantial evidence that the doctors agreed with Aventis to increase their usage of Taxotere and to submit false certifications that the claims were not tainted by an illegal kickback").

D. The SAC Is Not Barred by Public Disclosure

Defendants contend (Br. at 48) that Relator's action is barred by public disclosure because the fraud at issue was purportedly "publicly disclosed in congressional hearings, the news media, and federal reports." Defendants, however, entirely misconstrue the nature of the fraud alleged. With regard to Relator's actual allegations—*e.g.*, that Defendants were deceiving Medicare Part D beneficiaries as to whether less costly, generic drugs were available through formulary exceptions, denying formulary exceptions as a matter of course, and instructing CVS Pharmacies not to stock certain generics—Defendants have failed to establish that such allegations were publicly disclosed prior to the filing of Relator's complaint on June 11, 2019. In any event, because Relator qualifies as an original source, the public disclosure bar does not apply.

1. Relator's Allegations of Fraud Against Defendant Were Not Publicly Disclosed Prior to Relator's Action.

To obtain dismissal of an FCA action under the public disclosure bar, a defendant must show that "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A); *see also United States ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 303 (3d Cir. 2016) (defendant bears burden of

showing that public disclosure bar applies). "Whereas an 'allegation' of fraud is a specific allegation of wrongdoing, a 'transaction' that raises an inference of fraud consists of both the allegedly misrepresented facts and the allegedly true state of affairs." *United States ex rel. Silver v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018); *accord Moore*, 812 F.3d at 303.

Here, Defendants assert (Br. at 48-51) that the specific allegations of fraud were publicly disclosed through CMS materials, news articles, two civil cases, and a Senate Finance Committee hearing.[31] Defendants contend that these items publicly revealed SilverScript's preference for brand-name drugs over generic drugs on its formulary, that such preference could result in higher prices for both Part D beneficiaries and the Government, and that Defendants allegedly violated state mandatory generic-substitution laws through the use of incorrect DAW codes. As explained below, however, none of these public disclosures revealed "substantially the same allegations" as Relator alleges here.

First, Defendants point (Br. at 48-51) to SilverScript's Part D formularies (made public through CMS), various news articles, a Senate Finance Committee hearing, and a CMS report as revealing that Defendants preferred brand-name drugs over generic drugs, and that such preference could lead to increased costs for beneficiaries and the United States. Defendants' brand-name preference, however, is not the specific fraud that Relator alleges, but simply supplies the context in which Defendants' fraud occurred. The specific fraud that Relator alleges is that Defendants discouraged beneficiaries from seeking formulary exceptions for generic drugs (by misrepresenting the relative costs of brand-name drugs versus generic drugs), SAC ¶¶ 384, 388,

[31] Because Defendants make no argument that the same "transactions" were publicly disclosed, this Court need not address that alternate prong for dismissal under the public disclosure bar. *Cf. Silver*, 903 F.3d at 83 (where defendants did not argue that specific allegations of fraud had been publicly disclosed, court addressed only whether same transactions had been publicly disclosed).

440, 444, 508, 512, 518, 522, 635, 654, 658, denied all formulary exceptions for certain brand-name drugs (Harvoni/Epclusa), *id.* ¶¶ 14, 280, 500, 505, 508, 512, 515, 522, 540-554, 559, 577, 600, 605, 608, and ordered CVS pharmacies to not stock certain generic drugs, *id.* ¶¶ 15, 246-47, 264, 280, 319, 352, 500, 530. As a result, Part D beneficiaries were effectively denied access to generics, which would have resulted in lower costs for both the beneficiary and the Government. Instead, because of Defendants' fraudulent scheme to block access to generics through discouraging and denying formulary exceptions, Part D beneficiaries reached their Catastrophic Coverage limit sooner, resulting in greater costs to Medicare.

None of the publicly disclosed information Defendants rely upon revealed that Defendants had misled Part D beneficiaries about the costs of brand-name drugs versus generic drugs to discourage beneficiaries from seeking formulary exceptions, that Defendants had a policy to deny all Harvoni and Epclusa formulary exceptions, or that Defendants ordered CVS pharmacies not to stock generic drugs for Harvoni, Epclusa, Advair Diskus and Ventolin HFA. Nor were there any public disclosures revealing Defendants' breach of the 2007 FTC firewall, nor of the 2012 Consent Order.[32] Defendants make no argument that any of these allegations of fraud was publicly disclosed.

[32] Rather than revealing the collusion between the CVS Health entities that is alleged in the SAC, the purported public disclosure of the breach of CVS Health's 2007 FTC firewall to the Senate Finance Committee did not reveal fraud at all. Instead, CVS Health insisted that it was *complying* with the firewall, stating that: "Since CVS Pharmacy and Caremark merged, CVS Health has maintained stringent firewall protections between our CVS Pharmacy retail business and our CVS Caremark PBM business"; the FTC was "satisfied" that CVS and Caremark were "indeed kept separate"; "[t]here are many safeguards in place to" maintain the firewall; and "[t]he firewall . . . prohibits CVS/Caremark from sharing other confidential and competitive information, such as the reimbursement rates for its pharmacy networks, with the CVS/pharmacy segment." *Drug Pricing in America: A Prescription for Change, Part III: Hearing before the S. Comm. on Fin.*, 116th Cong. 415, 229 (2019) (statement of Derica Rice, Executive Vice President, CVS Health, and President, CVS Caremark), *available at* https://www.finance.senate.gov/imo/media/doc/435631.pdf.

And Defendants' assertion (Br. at 51) that the two *Fox Rx* cases publicly disclosed the same allegations of fraud here is also wrong. Defendants contend that those cases revealed Omnicare's and Walgreens' alleged violation of state mandatory generic-substitution laws through incorrect DAW codes. But, even assuming that allegation of fraud is the same as alleged here, which it is not, that fraud was allegedly perpetrated by completely different entities: Omnicare and Walgreens. Those cases, therefore, do not publicly disclose the same allegations of fraud. *See, e.g.*, *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 577 (9th Cir. 2016) ("Allowing a public document describing 'problems'—or even some generalized fraud . . . across a swath of an industry—to bar all FCA suits identifying specific instances of fraud in that . . . industry would deprive the government of information that could lead to recovery of misspent government funds and prevention of further fraud.").

Defendants, therefore, have failed to meet their burden of establishing that Relator's specific allegations of fraud against Defendants were publicly disclosed such that Relator's action should be dismissed. But, if there were any doubt, this Court should decline to dismiss Relator's action. *See, e.g.*, *United States ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 718 F. App'x 101, 104 (3d Cir. 2018) (public disclosure and original source issues are "matters of fact" such that a motion to dismiss should be granted only if nonmoving party "plead[s] itself out of the case"); *see Franchitti v. Cognizant Tech. Sols. Corp.*, 555 F. Supp. 3d 63, 72-73 (D.N.J. 2021).

2. In Any Event, Relator Is an Original Source, Precluding Application of the Public Disclosure Bar.

Even where the same allegations or transactions of fraud have been publicly disclosed, the Relator's claims are not barred if "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A). An original source "means an individual who either (i) prior to a public disclosure under subsection (e)(4)(A), has voluntarily disclosed to the

Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B).

Defendants argue (Br. at 52-53) that Relator cannot be an original source as a matter of law because Relator is not "an individual" within the meaning of 31 U.S.C. § 3730(e)(4)(B), but an entity. Defendants further contend (Br. at 53-54) that Relator has not adequately alleged that its knowledge is independent of and materially adds to the publicly disclosed allegations of fraud. Defendants are wrong on both counts.

It is not surprising that Defendants cite no case authority that an original source must be an "individual," as defined in 1 U.S.C. § 1, such that a corporation, company, association, firm, or partnership cannot be an original source, because no court has accepted Defendants' argument. Indeed, such an understanding runs contrary to this Circuit's case law, in which this Court concluded that a law firm could be an "original source" within the meaning of the FCA. *See Moore*, 812 F.3d at 304-08. Moreover, the Eighth Circuit has specifically rejected the argument that the original source exception applies only to individuals. *See Minnesota Ass'n of Nurse Anesthetists*, 276 F.3d 1032, 1048 n.12 (8th Cir. 2002). As the Eighth Circuit explained, "if examination of a statute shows 'no plausible reason why Congress would have intended to provide for . . . special treatment of actions filed by natural persons and to have precluded entirely . . . comparable cases brought by corporate persons,' . . . the word 'individual' does not limit the statute's scope to human beings." *Id.* (quoting *Clinton v. City of New York*, 524 U.S. 417, 429 (1998)). Because "[n]either the 1986 Amendments Act nor a review of its background or legislative history suggests that Congress meant to exclude suits on the basis of whether the relator

was a natural person, corporation, or association," the court rejected the argument that an original source was limited to natural persons. *Id.* For those same reasons, this Court should reject Defendants' argument that Relator here, because it is a limited liability partnership, cannot be an original source.

This Court should likewise reject Defendants' argument (Br. at 54) that Relator's knowledge is neither "independent of" nor "materially add[s] to" the public disclosures' allegations of fraud. The text of the original source exception "plainly requires courts to compare the relator's knowledge with the information that was disclosed through the public disclosure sources enumerated in § 3730(e)(4)(A)." *Moore*, 812 F.3d at 305. "The focus is now on what independent knowledge the relator has added to what was publicly disclosed." *Id.* at 299; *see also id.* at 304-05 (where relator alleged that its information was obtained through discovery in a different action, relator's knowledge was "independent of" the information revealed through public disclosures). "[T]o 'materially add[]' to the publicly disclosed allegation . . . a relator must contribute significant additional information to that which has been publicly disclosed so as to improve its quality." *Id.* at 305. The original source exception is met, therefore, when a relator "contributes information—distinct from what was publicly disclosed—that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Id.* at 307.[33]

[33] Defendants mistakenly rely (at 53-54) on *United States ex rel. Judd v. Quest Diagnostics Inc.*, 638 F. App'x 162 (3d Cir. 2015), but that case applied the pre-2010 version of the FCA, *id.* at 167, which required a relator to satisfy a higher hurdle to satisfy the original source exception, *Moore*, 812 F.3d at 298-99 (explaining that the 2010 FCA amendments "expanded the definition of 'original source,'" "evinc[ing] Congress's intent to lower the bar for relators"). The current iteration of the original source inquiry "requires an entirely different analysis." *Moore*, 812 F.3d at 305.

Relator easily satisfies this standard. First, Relator has alleged that its knowledge of the alleged fraud is independent of the purported public disclosures. Specifically, one of relator's partners, Alexandra Miller, was formerly employed by CVS Health for 19 years, during which time she obtained "firsthand, personal knowledge of the false claims, statements, and concealments alleged" in the complaint. *Id.* ¶¶ 33-36. Ms. Miller "has extensive personal knowledge and experience regarding" Defendants' conduct, as well as of alleged "violations of law" by CVS Health employees. *Id.* ¶ 34-36. In addition, Ms. Miller "conducted an independent investigation" into Defendants' actions. *Id.* ¶ 36. All of that knowledge serves as the basis for the SAC's allegations. Thus, the complaint plainly alleges that Relator has knowledge that is "independent of" the information revealed by the alleged public disclosures. *See Freedom Unlimited*, 718 F. App'x at 104-05 (where appellants "assert[ed] that they had independent material knowledge of" the alleged false claims, the motion to dismiss should have been denied). Defendants' suggestion to the contrary (Br. at 54) simply misconstrues the SAC.

Relator's knowledge also materially adds to the alleged public disclosures. The allegations in the SAC provide the "who, what, when, where, and how" of Defendants' fraudulent scheme and how it was carried out. For example, the SAC alleges that CVS Health asked Ms. Miller to informally monitor beneficiary grievances related to the unavailability of generic drugs to prevent a paper trail. SAC ¶¶ 115-19. The SAC further alleges how SilverScript blocked access to generic drugs and misled beneficiaries about their costs. *See, e.g.*, *id.* ¶ 238. CVS Health instructed SilverScript to "deny all formulary exceptions." *Id.* ¶ 246; *accord id.* ¶ 247 (SilverScript automatically denied formulary exceptions for generics); *id.* ¶ 280 ("blanket denials of formulary exceptions" began in late 2018); *id.* ¶¶ 319, 352. And CVS Pharmacies were likewise instructed not to stock the less costly generics. *See, e.g.*, *id.* ¶¶ 246, 280, 352. SilverScript also misled

beneficiaries as to the costs of generics to dissuade beneficiaries from seeking formulary exceptions. *See, e.g.*, *id.* ¶¶ 315, 341, 355, 359, 380, 381, 382. The SAC further details how Defendants' scheme was facilitated by the collusion of various CVS entities and the violation of firewalls. *See, e.g.*, *id.* ¶ 342. None of these facts, which add significant detail as to how Defendants implemented their scheme, harmed beneficiaries, and defrauded the Government, were included in any of the purported public disclosures. Defendants' assertion (Br. at 54) that Relator has failed to add any material facts to the public disclosures simply ignores all of these allegations.

E. CVS Health and CVS Pharmacy Are Proper Defendants.

Defendants argue CVS Health and CVS Pharmacy are "inappropriate" defendants (Br. at 14-15) because the SAC fails to allege either Defendant directly contracted with CMS under the Part D program or submitted claims for payment or created records in connection with a Part D program. Defendants are mistaken as to the allegations in the SAC and the relevant legal standard.

1. The SAC Plausibly Alleges CVS Health Is a Proper Defendant

The SAC alleges that the CVS Health Executive Committee, a standing committee of the CVS Health Board of Directors, specifically directed (over internal objections from Relator and others) that its subsidiaries would implement Defendants' fraudulent scheme, knowing it would impact Medicare Part D beneficiaries who would not be able to access cheaper generic drugs. SAC ¶¶ 15, 19, 35, 216, 263, 271, 287, 498, 503, 527, 529, 624, 627. There is no requirement under the FCA that CVS Health itself must have contracted with CMS under a Part D plan, or that it submitted claims for payment or submitted records in connection with such claims. Rather, the FCA's provisions on liability for those who cause false claims to be presented "indicate a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Schmidt*, 386 F.3d at 243. Likewise, unlike in *Polansky*, where the plaintiffs failed

to allege that the parent corporation had direct knowledge or involvement in the alleged fraud, *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 196 F. Supp. 3d 477, 512 (E.D. Pa. 2016), here the SAC alleges in detail that the CVS Health Executive Committee directed and controlled Defendants' scheme to block access to cheaper generic alternatives (SAC ¶¶ 18-19, 35, 216, 263) and are adequate at the pleadings stage. *See, e.g.*, *Sirls*, 469 F. Supp. 3d at 454 (allegations that parent company directed and controlled the fraud were adequate to survive motion to dismiss). At least one court has rejected this identical argument in another case involving CVS. In *United States ex rel. Bassan v. Omnicare, Inc.*, No. 1:15-CV- 4179 (CM), 2021 WL 1063784, at *13-14 (S.D.N.Y. Mar. 19, 2021), the court rejected the argument by CVS (now known as CVS Health), concluding the allegations of its active role "in overseeing [its subsidiaries'] operations and [CVS's] knowledge and involvement" in the fraudulent scheme are more than sufficient at the pleadings stage. *See also United States v. Planned Parenthood Fed'n of Am. Inc.*, No. 2:21-CV-022-Z, 2022 WL 1290907, at *12 (N.D. Tex. Apr. 29, 2022) (complaint alleging parent oversight over affiliates "surpasses the control exercised by a parent as an incident to ownership" and more than suffices to survive motion to dismiss). So, too, here.

2. Ellsworth Adequately Alleges CVS Pharmacy Is a Proper Defendant

Defendants fare no better with regard to their contention (Br. at 15) that the SAC fails to allege CVS Pharmacy directly participated in the fraud, asserting that it only dispenses drugs according to the Sponsor's instructions. It is well-settled in this Circuit that where a defendant's fraudulent conduct was a "substantial factor" in bringing about the presentation of a false claim by another party and the submission of the false claim was foreseeable or a "normal consequence" of the defendant's fraudulent conduct, then the defendant has "caused" a false claim to be submitted in violation of the FCA notwithstanding the fact that the provider who presented the false claim made an independent judgment in filing the claim. *Schmidt*, 386 F.3d at 244 (causation under FCA

sufficiently alleged where complaint plausibly suggests doctors wrote off-label prescriptions because of defendant Novartis' off-label marketing).

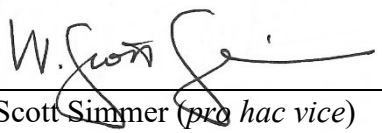
The Ellsworth allegations against CVS Pharmacy easily meet the *Schmidt* substantial factor requirements in three ways. *First*, the SAC alleges that CVS Pharmacy affirmatively joined in the fraudulent scheme by refusing to stock the cheaper authorized generic versions of Epclusa, Harvoni, Advair Diskus, and Ventolin HFA. SAC ¶¶ 15, 246-47, 264, 280, 319, 351-52, 500, 530, 624, 626-27. Even though it would lose money by not stocking the more profitable authorized generic drugs (*id.* at ¶¶ 264), CVS Pharmacy acted against its own interests and played a key role in Defendants' fraud by declining to stock these four generic drugs, conduct which was a substantial factor in blocking beneficiary access to these much cheaper drugs. *Id.* at ¶¶ 246-47, 351. *Second*, CVS Health ignores that the SAC alleges that Defendants' scheme required CVS Pharmacy to not comply with seventeen jurisdictions' mandatory generic substitution laws. *Id.* at ¶¶ 22, 175, 185, 188, 200, 207-11, 215, 219, 246, 249, 271, 305, 324-40, 398, 669. *Third*, the SAC alleges that CVS Pharmacy systematically reported false DAW codes to misrepresent what drugs were being dispensed and for what reasons. *See supra* pp. 30-34.

Contrary to what CVS Health contends now (*i.e.*, that CVS Pharmacy was simply a passive participant only following the instructions of the plan sponsor, *see* Br. at 15), its own internal documents told a different story. For example, its "Health Plan Client Strategy and FAQs" specifically states that compliance with state pharmacy laws mandating generic substitution "*are a pharmacy issue – and not a plan issue . . . .*" SAC ¶ 328 & Ex. 8 at CVS001795 (emphasis added). Thus, allegations concerning the CVS Pharmacy violation of state mandatory generic substitution laws (which its own documents make clear were a "pharmacy issue") are more than

sufficient at the pleadings stage to permit a conclusion that it was foreseeable that CVS Pharmacy's conduct would be a substantial factor in causing the submission of false claims.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motion to dismiss Relator's complaint.



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CERTIFICATE OF SERVICE

I certify that on September 23, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ W. Scott [illegible]